FORM 20-F

2021

sanofi

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

Or

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2021

Or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Or

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report

For the transition period from to

Commission File Number: 001-31368

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

France

(Jurisdiction of incorporation or organization)

54, rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Roy Papatheodorou , Executive Vice President, General Counsel & Head of Legal, Ethics and Business Integrity
54, rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of each exchange on which registered:
American Depositary Shares, each representing one half of one ordinary share, par value €2 per share	NASDAQ Global Select Market
Ordinary shares, par value €2 per share	NASDAQ Global Select Market*

Securities registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2021 was:

Ordinary shares: 1,263,560,695

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐.

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐.

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company. See definition of "large accelerated filer", "accelerated filer" or "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards[(1)] provided pursuant to Section 13(a) of the Exchange Act. ☐

(1) The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☒

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

International Financial Reporting Standards

U.S. GAAP ☐ as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒.

*Not for trading but only in connection with the registration of American Depositary Shares representing such ordinary shares.

Presentation of financial and other information

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS as endorsed by the European Union, as of December 31, 2021.

Unless the context requires otherwise, the terms “Sanofi”, the “Company”, the “Group”, “we”, “our” or “us” refer to Sanofi and its consolidated subsidiaries.

All references herein to “United States” or “US” are to the United States of America, references to “dollars” or “$” are to the currency of the United States, references to “France” are to the Republic of France, and references to “euro” and “€” are to the currency of the European Union member states (including France) participating in the European Monetary Union.

Brand names appearing in this annual report are trademarks of Sanofi and/or its affiliates, with the exception of:

- trademarks used or that may be or have been used under license by Sanofi and/or its affiliates, such as Actonel®, a trademark of Actavis or Procter & Gamble depending on the country; Aldurazyme®, a trademark of the Biomarin/Genzyme LLC Joint Venture; Cialis®, a trademark of Eli Lilly; Libtayo®, a trademark of Regeneron in the United States; Vaxelis®, a trademark of MSP Vaccine Company (USA) and MCM Vaccine B.V. (Netherlands); Zaltrap®, a trademark of Regeneron in the United States; Hyalgan®, a trademark of Fidia Farmaceutici S.p.A.; StarLink®, a trademark of Bayer;
- trademarks sold by Sanofi and/or its affiliates to a third party, such as Altace®, a trademark of King Pharmaceuticals in the United States;
- other third party trademarks such as Humalog®, a trademark of Eli Lilly; Eylea®, a trademark of Regeneron; Revlimid®, a trademark of Celgene Corporation; Velcade®, a trademark of Millennium Pharmaceuticals Inc; and Zantac®, a trademark of Glaxo Group Limited (except in the US and Canada);

Not all trademarks related to products under development have been authorized as of the date of this annual report by the relevant health authorities.

The data relating to market shares and ranking information for pharmaceutical products, in particular as presented in “Item 4. Information on the Company — B. Business Overview — B.6. Markets — B.6.1. Marketing and distribution”, are based mainly on sales data excluding vaccines and in constant euros (unless otherwise indicated) on a September 2021 MAT (Moving Annual Total) basis. The data are mainly from IQVIA local sales audit, supplemented by country-specific sources.

Product indications described in this annual report are composite summaries of the major indications approved in the product’s principal markets. Not all indications are necessarily available in each of the markets in which the products are approved. The summaries presented herein for the purpose of financial reporting do not substitute for careful consideration of the full labeling approved in each market.

Cautionary statement regarding forward-looking statements

This Annual Report contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. We may also make written or oral forward-looking statements in our periodic reports to the Securities and Exchange Commission on Form 6-K, in our annual report to shareholders, in our offering circulars and prospectuses, in press releases and other written materials and in oral statements made by our officers, directors or employees to third parties. Examples of such forward-looking statements include:

- projections of operating revenues, net income, business net income, earnings per share, business earnings per share, capital expenditures, cost savings, restructuring costs, positive or negative synergies, dividends, capital structure or other financial items or ratios;
- statements of our profit forecasts, trends, plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition; and
- statements about our future events and economic performance or that of France, the United States or any other countries in which we operate.

This information is based on data, assumptions and estimates considered as reasonable by Sanofi as at the date of this annual report and undue reliance should not be placed on such statements.

Words such as “believe”, “anticipate”, “plan”, “expect”, “intend”, “target”, “estimate”, “project”, “predict”, “forecast”, "ambition", “guideline”, “should” and similar expressions are intended to identify forward-looking statements but are not the exclusive means of identifying such statements.

Forward-looking statements involve inherent, known and unknown risks and uncertainties associated with the regulatory, economic, financial and competitive environment, and other factors that could cause future results and objectives to differ materially from those expressed or implied in the forward-looking statements.

Risk factors which could affect future results and cause actual results to differ materially from those contained in any forward-looking statements are discussed under “Item 3. Key Information — D. Risk Factors”. Additional risks, not currently known or considered immaterial by the Group, may have the same unfavorable effect and investors may lose all or part of their investment.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments.

Abbreviations

Principal abbreviations used in the Annual Report on Form 20-F

ADR	American Depositary Receipt
ADS	American Depositary Share
AFEP	*Association française des entreprises privées* (French Association of Large Companies)
AMF	*Autorité des marchés financiers* (the French market regulator)
ANDA	Abbreviated New Drug Application
BLA	Biologic License Application
BMS	Bristol-Myers Squibb
CEO	Chief Executive Officer
CER	Constant exchange rates
CGU	Cash generating unit
CHC	Consumer Healthcare
CHMP	Committee for Medicinal Products for Human Use
COVALIS	Sanofi committee for internal occupational exposure limits (Comité des Valeurs Limites Internes Sanofi)
CVR	Contingent value right
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union
FCF	Free cash flow
FDA	US Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunisation
GBU	Global Business Unit
GCP	Good clinical practices
GDP	Good distribution practices
GLP	Good laboratory practices
GLP-1	Glucagon-like peptide-1
GMP	Good manufacturing practices
Hib	Haemophilus influenzae type b
HSE	Health, Safety and Environment
IASB	International Accounting Standards Board
ICH	International Council for Harmonization
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IFRIC	International Financial Reporting Interpretations Committee
IFRS	International Financial Reporting Standards
IPV	Inactivated polio vaccine
ISIN	International Securities Identification Number
J-MHLW	Japanese Ministry of Health, Labor and Welfare
LSD	Lysosomal storage disorder
MEDEF	*Mouvement des entreprises de France* (French business confederation)
MS	Multiple sclerosis
NASDAQ	National Association of Securities Dealers Automated Quotations
NDA	New Drug Application
NHI	National Health Insurance (Japan)
NYSE	New York Stock Exchange
OECD	Organisation for Economic Co-operation and Development
OPV	Oral polio vaccine
OTC	Over the counter
PhRMA	Pharmaceutical Research and Manufacturers of America
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PRV	Priority Review Voucher
PTE	Patent Term Extension
QIV	Quadrivalent influenza vaccine
R&D	Research and development
ROA	Return on assets
SA	*Société anonyme* (French public limited corporation)
SEC	US Securities and Exchange Commission
SPC	Supplementary Protection Certificate
TRIBIO	Sanofi Committee for Biological Risk Prevention (Biosafety, Biosecurity, Biosurveillance)
TSR	Total shareholder return
UNICEF	United Nations Children's Emergency Fund
US	United States of America
WHO	World Health Organization

TABLE OF CONTENTS

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Part I

Item 1. Identity of Directors, Senior Management and Advisers

N/A

Item 2. Offer Statistics and Expected Timetable

N/A

Item 3. Key Information

A. Selected financial data

N/A

B. Capitalization and indebtedness

N/A

C. Reasons for offer and use of proceeds

N/A

D. Risk factors

Important factors that could cause actual financial, business, research or operating results to differ materially from expectations are disclosed in this annual report, including without limitation the following risk factors. Investors should carefully consider all the information set forth in the following risk factors and elsewhere in this document before deciding to invest in any of the Company's securities. In addition to the risks listed below, we may be subject to other material risks that as of the date of this report are not currently known to us or that we deem immaterial at this time.

Risks relating to legal and regulatory matters

Product liability claims could adversely affect our business, results of operations and financial condition

Product liability is a significant risk for any pharmaceutical company and our product liability exposure could increase, given that liability claims relating to our businesses may differ – with regard to their nature, scope and level – from the types of product liability claims that we have handled in the past. Substantial damages have been awarded by some jurisdictions and/or settlements agreed – notably in the United States and other common law jurisdictions – against pharmaceutical companies based on claims for injuries allegedly caused by the use of their products. Such claims can also lead to product recalls, withdrawals, or declining sales, and/or be accompanied by consumer fraud claims by customers, third-party payers seeking reimbursement of the cost of the product and/or other claims, including potential civil or criminal governmental actions.

We are currently defending a number of product liability claims (see Note D.22.a.) to the consolidated financial statements included at Item 18. of this annual report) notably with respect to Taxotere®, Zantac® and Depakine® and there can be no assurance that we will be successful in defending these claims, or that we will not face additional claims in the future.

Establishing the full side effect profile of a pharmaceutical drug goes beyond data derived from preapproval clinical studies which may only involve several hundred to several thousand patients. Routine review and analysis of the continually growing body of post-marketing safety data and clinical trials provide additional information – for example, potential evidence of rare, population-specific or long-term adverse events or of drug interactions that were not observed in preapproval clinical studies. This causes product labeling to evolve over time following interactions with regulatory authorities, which may include restrictions of therapeutic indications, new contraindications, warnings or precautions and occasionally even the suspension or withdrawal of a product marketing authorization. Following any of these events, pharmaceutical companies can face significant product liability claims (see Note D.22.a.) to the consolidated financial statements included at Item 18. of this annual report).

Furthermore, we commercialize several devices (some of which use new technologies) which, if they malfunction, could cause unexpected damage and lead to product liability claims (see "Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, business or reputational harm" below).

Although we continue to insure a portion of our product liability with third-party carriers, product liability coverage is increasingly difficult and costly to obtain, particularly in the United States. In the future, it is possible that self-insurance may become the sole commercially reasonable means available for managing the financial risk associated with product liability in our pharmaceuticals and vaccines businesses (see "Item 4. Information on the Company — B. Business Overview — B.9. Insurance and Risk Coverage"). In cases where we self-insure, the legal costs that we would bear for handling such claims, and potential damage awards to be paid to claimants, could have a negative impact on our financial condition. Due to insurance conditions, even when we have insurance coverage, recoveries from insurers may not be totally successful due to market-driven insurance limitations and exclusions. Moreover, insolvency of an insurer could affect our ability to recover claims on policies for which we have already paid a premium.

Product liability claims, regardless of their merits or the ultimate success of the Company's defense, are costly, divert management's attention, may harm our reputation and can impact the demand for our products. Substantial product liability claims could materially adversely affect our business, results of operations and financial condition.

Claims and investigations relating to ethics and business integrity, competition law, marketing practices, pricing, human rights of workers, data protection and other legal matters could adversely affect our business, results of operations and financial condition

Our industry is heavily regulated and legal requirements vary from country to country, and new requirements are imposed on our industry from time to time. Governments and regulatory authorities around the world have been strengthening implementation and enforcement activities in recent years, including in relation to anti-bribery, anti-corruption and ethical requirements with respect to medical and scientific research, interactions with healthcare professionals and payers, respect of the human rights of workers, and data protection legislation. We also operate in an environment that relies on the collection, processing, analysis and interpretation of large sets of patients' and other individuals' personal information, and the operation of our business requires data to flow freely across borders of numerous countries.

We have adopted a Code of Ethics that requires employees to comply with applicable laws and regulations, as well as the specific principles and rules of conduct set forth in the Code. We also have policies and procedures designed to help ensure that we, our officers, employees, agents, intermediaries and other third parties comply with applicable laws and regulations (including but not limited to the US Foreign Corrupt Practices Act ("FCPA"), the UK Bribery Act, the OECD Anti-Bribery Convention, the French Anti-Corruption measures law ("Sapin II"), the French duty of vigilance law and other anti-bribery laws and regulations).

Notwithstanding these efforts, failure to comply with laws and regulations (including as a result of a business partner's breach) may occur and could result in liabilities for us and/or our management.

With respect to data protection legislation, violations of the European General Data Protection Regulation ("GDPR"), which came into force in 2018, or other significant new privacy legislation, including in the United States the California Consumer Privacy Act ("CCPA") among others, could carry financial sanctions and may also harm our reputation and those of our activities that rely on personal data processing. Violations of the GDPR carry financial risks due to penalties for data breach or improper processing of personal data (including a possible fine of up to 4% of total worldwide annual turnover for the preceding financial year for the most serious infringements). In addition, some uncertainty remains with respect to the legal and regulatory environment for these evolving privacy and data protection laws in the absence of clear guidance or case law.

Sanofi and certain of its subsidiaries could become the subject of investigations or proceedings by various government entities or could face audits and/or litigation, including allegations of corruption, claims related to employment matters, patent and intellectual property disputes, consumer law claims and tax audits. We are currently defending ourselves in a number of lawsuits relating to pricing and marketing practices (including, for example, "whistleblower" litigation in the United States). With respect to tax issues, the complexity of the fiscal environment is such that the ultimate resolution of any tax matter may result in payments that are greater or less than the amounts we have accrued. See "Item 8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings" and Note D.22. to our consolidated financial statements included at Item 18. of this annual report. In addition, responding to such investigations is costly and may divert management's attention from our business.

Unfavorable outcomes in any of these matters, or in similar matters that may arise in the future, could preclude the commercialization of our products, harm our reputation, negatively affect the profitability of existing products and subject us to substantial fines, punitive damages, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls, monitoring or self-reporting obligations, or exclusion from government reimbursement programs or markets, all of which could have a material adverse effect on our business, results of operations or financial condition.

The unpredictability of these proceedings could lead Sanofi, after consideration of all relevant factors, to enter into settlement agreements to settle certain claims. Such settlements may involve significant monetary payments and/or potential criminal penalties, and may include admissions of wrongdoing and may require entering into a Corporate Integrity Agreement ("CIA") or a Deferred Prosecution Agreement (in the United States), which is intended to regulate company behavior for a specified number of years. For example, on February 28, 2020, Sanofi US entered into a civil settlement with the United States Department of Justice and agreed to pay approximately $11.85 million to resolve allegations regarding certain charitable donations Sanofi US made to an independent patient assistance foundation that assisted patients being treated for Multiple Sclerosis. In connection with this settlement, Sanofi US also entered into a CIA with the Office of the Inspector General for the United States Department of Health and Human Services effective the same day, which will require the Company to meet and maintain certain compliance requirements in the United States.

Our activities (including our products and manufacturing activities) are subject to significant government regulations and regulatory approvals, which are often costly and could result in adverse consequences to our business if we fail to anticipate the regulations, comply with them, maintain the required approvals, and/or adapt to changes in applicable regulations

Obtaining a marketing authorization for a product is a long and highly regulated process requiring us to present extensive documentation and data to the relevant regulatory authorities either at the time of the filing of the application for a marketing authorization or later during its review. Each regulatory authority may impose its own requirements which can evolve over time. Each regulatory authority may also delay or refuse to grant approval even though a product has already been approved in another country. Regulatory authorities are increasingly strengthening their requirements on product safety and risk/benefit profile. All of these requirements, including post-marketing requirements, have increased the costs associated with maintaining marketing authorizations.

Moreover, to monitor our compliance with applicable regulations, the FDA, EMA, WHO and comparable national agencies in other jurisdictions routinely conduct regulatory inspections of our facilities, distribution centers, commercial activities and development centers and may identify potential deficiencies. For example, in November 2020, the FDA issued a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) for sutimlimab, an investigational monoclonal antibody being studied for the treatment of hemolysis in adults with cold agglutinin disease, referring to certain deficiencies identified by the agency during a pre-license inspection of a third-party facility responsible for manufacturing. More generally, if we fail to adequately respond to regulatory inspection observations identified during an inspection, or fail to comply with applicable regulatory requirements at all or within the targeted timeline, we could be subject to enforcement, remedial and/or punitive actions by the FDA (such as a Warning Letter, injunction or seizure cease and desist order), the EMA or other regulatory authorities. In addition, we have an obligation to monitor and report adverse events and safety signals. In order to comply with our duty to report adverse events and safety signals, we must regularly train our employees and certain third parties (such as external sales forces and distributor employees) on regulatory matters, including on pharmacovigilance. If we fail to train these people, or fail to train them appropriately, or if they do not comply with contractual requirements, we may be exposed to the risk that safety events are not reported or not reported in a timely manner in breach of our reporting obligations.

In addition, all aspects of our business, including research and development, manufacturing, marketing, reimbursement, pricing and sales, are subject to extensive legislation and governmental regulation. Changes in applicable laws and the costs of compliance with such laws and regulations could have an adverse effect on our business.

For example, in response to the new European Union regulations for Medical Devices (EU MDR), the entry into force of which was postponed from May 2020 to May 2021, Sanofi created the EU MDR task force. This task force was commissioned to address the risk of potential delays in approvals (for new drug-device combination products, for substantial changes to the design or intended purpose of the device component of already approved drug-device combination products, and for Medical Devices) and of product discontinuation (for some legacy medical devices), as well as compliance risks for existing products due to increased requirements for post-marketing surveillance, clinical evaluations, traceability and transparency. A similar task force was set up in the first quarter of 2021 to examine risks related to the new regulations for In-Vitro Diagnostic Devices (IVDR) due to be implemented in May 2022.

For information about risks related to changes:

- in proprietary rights rules and regulations, see "– We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products. If such patents and other rights were limited, invalidated or circumvented, our financial results could be adversely affected" below; and
- in environmental rules and regulations, see "– Management of the historical contamination related to our past industrial activities may have a significant adverse effect on our results of operations" below.

We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products. If such patents and other rights were limited, invalidated or circumvented, our financial results could be adversely affected

Through patent and other proprietary rights, such as data exclusivity or supplementary protection certificates in Europe, we hold exclusivity rights for a number of our research-based products. However, the protection that we are able to obtain varies in its duration and scope. Furthermore, patents and other proprietary rights do not always provide effective protection for our products.

For example, governmental authorities are increasingly looking to facilitate generic and biosimilar competition for existing products through new regulatory proposals intended to achieve, or resulting in, changes to the scope of patent or data exclusivity rights and through the use of accelerated regulatory pathways for generic and biosimilar drug approvals. Such regulatory proposals could make patent prosecution for new products more difficult and time consuming or could adversely affect the exclusivity period for our products.

Moreover, manufacturers of generic products or biosimilars are increasingly seeking to challenge patent validity or coverage before the patents expire, and manufacturers of biosimilars or interchangeable versions of the products are seeking to have their version of the product approved before the exclusivity period ends. Furthermore, in an infringement suit against a third party, we may not prevail and the decision rendered may not conclude that our patent or other proprietary rights are valid, enforceable or infringed. Our competitors may also successfully avoid our patents. Even in cases where we ultimately prevail in an infringement claim, legal remedies available for harm caused to us by infringing products may be inadequate to make us whole. Moreover, a successful result against a competing product for a given patent or in a specific country is not necessarily predictive of our future success against another competing product or in another country because of local variations in the patents and patent laws.

In addition, if we lose patent protection as a result of an adverse court decision or a settlement, we face the risk that government and private third-party payers and purchasers of pharmaceutical products may claim damages alleging they have over-reimbursed or overpaid for a drug. For example, in Australia, our patent on clopidogrel was ultimately held invalid. Following this decision, the Australian Government sought damages for its alleged over-reimbursement of clopidogrel drugs due to the preliminary injunction we had secured against the sale of generic clopidogrel during the course of the litigation. The Australian Government's claim was dismissed following a

decision of the Federal Court of Australia on April 28, 2020. Sanofi is awaiting the judgment to be delivered by the Federal Court of Australia, following the appeal of the first instance decision by the Australian Government on May 26, 2020.

In certain cases, to terminate or avoid patent litigation we or our collaboration partners may be required to obtain licenses from the holders of third-party intellectual property rights. Any payments under these licenses may reduce our profits from such products and we may not be able to obtain these licenses on favorable terms or at all.

Third parties may also request a preliminary or permanent injunction in a country from a court of law to prevent us from marketing a product if they consider that we infringe their patent rights in that country. For example, Sanofi is or was party to patent infringement proceedings in several countries initiated against us and Regeneron by Amgen relating to Praluent® in which Amgen requested injunctive relief (see Note D.22.b.) to the consolidated financial statements included at Item 18. of this annual report for more information). If third parties obtain a preliminary or permanent injunction or if we fail to obtain a required license for a country where valid third-party intellectual property rights as confirmed by a court of law exist, or if we are unable to alter the design of our technology to fall outside the scope of third-party intellectual property rights, we may be unable to market some of our products in certain countries, which may limit our profitability.

Furthermore, some countries may consider granting a compulsory license to a third party to use patents protecting an innovator's product, which limits the value of the patent protection granted to such products.

We have increased the proportion of biological therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. Typically, the development, manufacture, sale and distribution of biological therapeutics is complicated by third-party intellectual property rights (otherwise known as freedom to operate (FTO) issues), to a greater extent than for the small molecule therapeutics, because of the types of patents allowed by national patent offices. Further, our ability to successfully challenge third-party patent rights is dependent on the legal interpretation and case law of national courts. In addition, we expect to face increasing competition from biosimilars in the future. With the accelerated regulatory pathways provided in the United States and Europe for biosimilar drug approval, biosimilars can be a threat to the exclusivity of any biological therapeutics we sell or may market in the future and can pose the same issues as the small molecule generic threat described above. If a biosimilar version of one of our products were to be approved, it could reduce our sales and/or profitability of that product.

If our patents and/or proprietary rights to our products were limited or circumvented, our financial results could be adversely affected.

Risks relating to our business

The pricing and reimbursement of our products is increasingly affected by cost containment pressures and decisions of governments and other third parties

The commercial success of our existing products and our product candidates depends in part on their pricing and the conditions under which they are reimbursed. At a time of intense scrutiny over drug prices, our products continue to be negatively affected by downward pressure due, inter alia, to:

- stricter price and access controls imposed by governments and other payers in most countries:
  - requirements for greater transparency around of drug pricing and drug development costs,
  - widespread use of international reference pricing and therapeutic reference pricing, among other pricing methodologies and caps,
  - mandatory price cuts, renegotiations, industry payback and rebates,
  - shifting of the payment burden to patients through higher copayments and co-pay accumulator programs,
  - delisting from reimbursement and restrictions on the label population,
  - access restrictions for high-priced innovative medicines,
  - tighter formulary management (including stepped therapy, strict prior authorization criteria; formulary exclusions) mainly by insurers and pharmacy benefit managers (PBMs) in the United States,
  - prescribing guidelines and binding medicine utilization controls,
  - greater use of tendering and centralized procurement (national/regional/class-wide level),
  - cross-country cooperation in price negotiations, contracting or procurement, already occurring to some extent (for example COVAX initiative, the BeNeLuxA alliance in Europe, South America/PAHO arrangements),
  - discriminatory and non-transparent pricing and procurement policies (e.g. government procurement restrictions, import bans) in favor of domestic pharmaceutical companies, and
  - additional complexity in the access environment created by the COVID-19 Pandemic, resulting in budget constraints;
- widespread use of health technology assessment (HTA) to inform coverage and reimbursement decisions:
  - more stringent evidence and value requirements (e.g. comparative effectiveness, patient preferences, real-word evidence, health economic modelling) by payers and HTA authorities, raising the bar for market entry,
  - unreasonable thresholds for cost-effectiveness, and
  - increasingly restrictive HTA decisions with significant variation across markets;
- loss of exclusivity, and generic and biosimilar competition, accelerating price erosion:
  - increasing penetration of generics globally (e.g. nearly 90% of prescription drugs dispensed in the US in 2020),
  - next generation of biosimilars coming to the market across major therapeutic areas,

– savings potential from increased biosimilar use (expected to be a cumulative $285 billion globally through 2025 according to the IQVIA Institute), and

– evolving regulatory landscapes to support interchangeability (e.g. US) and pharmacy substitution (e.g. EU Nordics, Germany).

In the United States, which accounted for 38.1% of our net sales in 2021, the government's focus remains on handling the COVID-19 pandemic. There remains a significant risk that the US Congress could enact substantial policy reforms in 2022, or that the Administration could use its executive authority to pass drug pricing legislation, with a potentially detrimental impact on pharmaceutical innovation and pricing. Other risks include the increasing focus on price transparency, and the growing interest in "Buy American" procurement rules. Finally, there are persistent supply chain challenges due to high dependency on API imports from China and India. If we had to source API from the US where they are more expensive, the current cost containments would not allow us to reflect the corresponding increase on our prices which would impact the margins of our products.

In addition, the continued consolidation of the US pharmacy benefits management market exposes us to greater pricing pressure. With the largest three PBMs/Group Purchasing Organizations – OptumRx (Emisar), CVS/Caremark (Zinc), and Express Scripts (Ascent) – now covering over 85% of US prescription claims, consolidation has led to more aggressive formulary management of specialty medicines and larger rebates in return for access. The rise of drug formulary exclusions, in favor of lower-cost therapeutic alternatives, may result in a significant reduction in sales.

In China, we continue to face increasingly fierce local competition in a market that is highly fragmented and dominated by multiple stakeholders.

The National Healthcare Security Administration (NHSA) plays an increasing role in centralizing drug procurement and pursuing aggressive pricing policies, forcing us to drastically reduce prices to gain access to China's pharmaceutical market.

We expect competitive and pricing pressure to intensify across our portfolio as a growing number of our products are subject to national reimbursement drug list (NRDL) price negotiations and national volume-based procurement (VBP) tenders, with the lowest price prevailing.

Oncology products, in particular, are experiencing greater price cuts due to increased competition from domestic manufacturers in NRDL negotiations, especially in the PD-1 inhibitor space. In 2020, only Chinese PD-1 inhibitors were added to the NRDL (while imported drugs in the therapeutic class failed to pass the negotiation phase), signaling additional access challenges for innovative oncology therapies in China.

Further expansion of the VBP policy to biologics and biosimilars also poses a major and growing threat to our key established products moving forward. Although there is still uncertainty around the mechanism for the inclusion of the insulin class in the sixth national VBP round, we expect our diabetes sales will be impacted in 2022.

Due to these competitive pressures on our prices, our revenues and margins are, and could continue to be, negatively affected.

In Europe, in November 2020, the European Commission (EC) adopted a new Pharmaceutical Strategy for Europe that may result in higher constraints and lower innovation rewards, posing downside risks across our pipeline portfolio.

The Commission's most concerning proposals relate to revamping incentives in unmet need areas such as rare and pediatric diseases, allowing earlier market entry of generics and biosimilars, promoting greater transparency around pricing and drug development costs, and cross-border collaboration on pricing and procurement.

Our research and development efforts may not succeed in adequately renewing our product portfolio

Discovering and developing a new product is a costly, lengthy and uncertain process. To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products to compensate for decreasing sales of products facing patent expiration and termination of regulatory data exclusivity, introduction of lower-priced generics, or competition from new products of competitors that are perceived as being superior or equivalent to our products. We must pursue both early-stage research and early and late development stages in order to propose a sustainable and well-balanced portfolio of products. In 2021, we spent €5,692 million on research and development, amounting to 15.1% of our net sales. Failure to invest in the right technology platforms, therapeutic areas, product classes, geographic markets and/or licensing opportunities could adversely impact the productivity of our pipeline.

We prioritize six potentially transformative therapies in areas of high unmet patient need: fitusiran and BIVV001/efanesoctocog alfa (hemophilia); amcenestrant (breast cancer); amlitelimab (atopic dermatitis); nirsevimab (respiratory syncytial virus); and tolebrutinib (multiple sclerosis). We also announced our decision to discontinue our research efforts in diabetes and cardiovascular diseases and refocus our R&D strategy on oncology, immunology and inflammation, multiple sclerosis and neurology and rare diseases and rare blood disorders. In 2021, Sanofi acquired Translate Bio to accelerate the deployment of mRNA technology for the development of new vaccines, including for seasonal influenza, and beyond vaccines, therapeutics where there is a strong unmet medical need. However, mRNA technology is still in its very early days and the ability of this technology to demonstrate strong results and safety still remains to be asserted; we may also fail to improve our development productivity sufficiently to sustain our pipeline (see also "– We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments or divestments" below). In addition, the competitive landscape includes a high level of uncertainty as numerous companies are working on or may be evaluating similar targets and a product considered as promising at the beginning of its development may become less attractive if a competitor addressing the same unmet need reaches the market earlier. There can be no assurance that any of our product candidates will be proven safe or effective (see "Item 4. Information on the Company — B. Business Overview — B.5. Global Research & Development"). Over these research and development cycles, usually spanning several years, there is a substantial risk at each stage of development – including pre-clinical activities and clinical trials – that we will not achieve our goals of safety and/or efficacy and that we will have to abandon a product in which we have invested substantial amounts of money and human resources. More and more trials are designed with clinical endpoints of superiority; failure to achieve those endpoints could damage the product's outlook and our overall development program.

Decisions concerning the studies to be carried out can have a significant impact on the marketing strategy for a given product. Multiple in-depth studies can demonstrate that a product has additional benefits, facilitating the product's marketing, but such studies are expensive and time consuming and may delay the product's submission to regulatory authorities for approval.

In addition, following (or in some cases contemporaneously with) the marketing authorization, the dossier is also submitted to governmental agencies and/or national or regional third-party payers (HTA bodies) for review. These HTA bodies evaluate evidence on the value of the new product, assess the medical need it serves, and provide recommendations on the corresponding reimbursement. Such analyses may require additional studies, including comparative studies, which may effectively delay marketing, change the population which the new product treats, and add costs to its development. Our continuous investments in research and development for future products and for the launches of newly registered molecules could therefore result in increased costs without a proportionate increase in revenues, which would negatively affect our operating results and profitability.

Lastly, there can be no assurance that all the products approved or launched will achieve commercial success.

Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, business or reputational harm

Our business depends heavily on the use of interdependent information technology systems, including internet-based systems and digital tools. Certain key areas such as research and development, production and sales are to a large extent dependent on our information systems (including cloud-based computing) or those of third-party providers (including for the storage and transfer of critical, confidential, sensitive or personal information regarding our patients, clinical trials, vendors, customers, employees, collaborators and others). We are therefore vulnerable to cybersecurity attacks and incidents and misuse or manipulation of any of these IT systems could result in exposure of confidential information or the modification of critical data.

We and our third-party service providers, suppliers, contract manufacturers, distributors or other contracting third parties use, to the best of our ability, secure information technology systems for the protection of data and threat detection. Like many companies, we may experience certain of the following events which pose a risk to the security and availability of these systems and networks, and the confidentiality, integrity, and availability of the Company's sensitive data: breakdown, outages, service disruption or impairment, data loss or deterioration in the event of a system malfunction or increasing threat of data theft or corruption in the event of a cyber-attack, security breach, industrial espionage attacks, insider threat attacks, cybercrimes, including state-sponsored cybercrimes, malware, misplaced or lost data, programming or human errors or other similar events. The pandemic has both exacerbated attacks related to competitive intelligence by criminal organizations targeting information related to COVID-19 research, development, and production and increased the opportunity for such attacks as remote working has become more widely used, and sensitive data is accessed by employees working in less secure, home-based environments. Also, in the event of an attack, US and European legislation related to the financing of terrorism imposes increasing restrictions on payments of ransom. As a result, our ability to recover the data might be limited. Therefore, our business continuity could be at risk if we are unable to recover data through back-ups and restorations.

Each of these events could negatively impact important processes, such as scientific research and clinical trials, the submission of outcomes to health authorities for marketing authorizations, the functioning of production processes and the supply chain, compliance with legal requirements, trade secrets, security strategies and other key activities, including Sanofi's employees' ability to communicate between themselves as well as with third parties (see also "– Product liability claims could adversely affect our business, results of operations and financial condition" above). This could result in material financial, legal, competitive, operational, business or reputational harm.

Although we maintain relevant insurance coverage, this insurance may not be sufficiently available in the future to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. For example, certain types of cyber-attacks could be considered as an Act of War subject to insurance exclusion.

The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products and negatively impact our image

Many of our products are manufactured using technically complex processes with production constraints, including the need for specialized facilities, trained and certified employees, and highly specific raw materials. We must ensure that all manufacturing processes comply with (i) current Good Manufacturing Practices (cGMP), (ii) other applicable regulations issued by governmental health authorities around the world, as well as (iii) our own quality standards. Third parties supply us with a portion of our raw materials, active ingredients and medical devices, which exposes us to the risk of a supply shortage or interruption in the event that these suppliers are unable to manufacture our products in line with quality standards or if they experience financial difficulties. For example, in 2021 Genzyme sold a manufacturing facility located in Allston Landing in the United States to a third party, which is in particular involved in the production of Cerezyme®. We now rely on that third party for certain manufacturing and testing operations pursuant to the terms and conditions of relevant contractual agreements with such third party. The manufacturing and testing operations performed on Genzyme's behalf at the Allston Landing facility are subject to the terms of a consent decree requiring ongoing compliance therewith, which was entered into between Genzyme and the US government in 2010. We now rely on the third party that acquired the Allston Landing site to perform manufacturing and testing services on our behalf and to ensure compliance with the terms and conditions of the aforementioned consent decree. We could be subject to product supply risk if the third party is unable to supply product to us and to regulatory action if the third party acquirer of the Allston Landing site fails to comply with applicable laws and regulations, including cGMP, when performing the relevant services.

Epidemics and other public health crises, such as the ongoing coronavirus pandemic, expose us to risks of a slowdown or temporary suspension in the production of our active pharmaceutical ingredients (API), raw materials, and some of our products. Any prolonged restrictive measures put in place in order to control an outbreak of contagious disease or other adverse public health development, in any of our principal production sites, may have a material and adverse effect on our manufacturing operations. Any of these factors could adversely affect our business, operating results or financial condition (see "Item 4. Information on the Company — B. Business Overview

— B.8. Production and Raw Materials" for a description of these outsourcing arrangements and "The extent to which the COVID-19 pandemic and related developments, including measures implemented in response thereto, may impact our business, operations and financial performance is highly uncertain and difficult to predict" below).

Our business may require the transformation and adaptation of our plants in order to ensure the continuity of production of our products in sufficient quantities to satisfy demand. This may be necessary to meet the need for the production of new products, including biologics, or to ensure the scaling up production of products under development once approved. This need may also result from new regulatory requirements; for example, the fact that insulin is no longer regulated by the FDA as a drug but rather as a biologic requires significant transformation and adaptation of our insulin manufacturing plant in Frankfurt, with no guarantee that we will manage to complete that plan within the expected time. Furthermore, our biological products, in particular, are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent in the processing of biological materials and the potential difficulties in accessing adequate amounts of raw materials meeting required standards. In addition, specific storage and distribution conditions are required for many biological products (for example, cold storage is required for certain vaccines, insulin-based products and some hemophilia products). These production difficulties may also be encountered during testing, which is a mandatory requirement prior to drug products being released. For example, in 2018 in China, we encountered supply constraints of Pentaxim® vaccine due to problems with the supplier of a raw material used in the formulation of this vaccine in China. As a result, we had to find an alternative raw material to meet Chinese requirements.

Some of our production sites, and some of our suppliers' and/or contractors' sites, are located in areas exposed to natural disasters such as floods, earthquakes and hurricanes. Such disasters could be exacerbated by climate change. In the event of a major disaster, we could experience severe destruction or interruption of our operations and production capacity at these sites. The complexity of these processes, as well as standards required for the manufacture of our products, subject us to risks because the investigation and remediation of any identified or suspected problems can cause production delays, substantial expense, product recalls or lost sales and inventories, and delay the launch of new products; this could adversely affect our operating results and financial condition, and cause reputational damage and the risk of product liability (see "– Product liability claims could adversely affect our business, results of operations and financial condition" above).

When manufacturing disruptions occur, we may not have alternate manufacturing capacity, particularly for certain biologics. In the event of manufacturing disruptions, our ability to use backup facilities or set up new facilities is more limited because biologics are more complex to manufacture and generally require dedicated facilities. Even though we aim to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principal active ingredients at additional facilities when practicable, we cannot be certain they will be sufficient if our principal sources become unavailable. Switching sources and manufacturing facilities requires significant time and prior approval by health authorities.

Supply shortages generate even greater negative reactions when they occur with respect to life saving medicines with limited or no viable therapeutic alternatives. Shortages of specific products can have a negative impact on the confidence of patients, customers and professional healthcare providers and the image of Sanofi and may lead to lower product revenues.

A substantial share of the revenue and income of Sanofi depends on the performance of certain flagship products

As part of the presentation of our strategy in December 2019 we announced our intent to prioritize our activities on growth drivers including Dupixent® and our Vaccines operations, which we have identified as key growth drivers. Nevertheless market expansion and new launches of medicines and vaccines may not deliver the expected benefits. We may also encounter failures or delays in our launch strategy (in terms of timing, pricing, market access, marketing efforts and dedicated sales forces), such that our products that may not deliver the expected benefits. The competitive environment for a given product may also have changed by the time of the actual launch, modifying our initial expectations. The need to prioritize the allocation of resources may also cause delays in or hamper the launch or expansion of some of our products.

Also, we currently generate a substantial share of our net sales from certain key products (see "Item 5. Operating and Financial Review and Prospects — A.2. Results of Operations — Year ended December 31, 2021 compared with year ended December 31, 2020 — A.2.1.3/ Net Sales — Pharmaceuticals segment"). For example, Dupixent® generated net sales of €5,249 million in 2021 representing 13.9% of our net sales for the year and is Sanofi biggest product in terms of sales .

Among our flagship products, Lantus®, Lovenox® and Plavix® already face generic competition on the market. Lantus® is particularly important; it was one of Sanofi's leading products in 2021 with net sales of €2,494 million. Aubagio®, another leading product, is expected to face generic competition in the US starting from March 2023, following a settlement agreement entered into in 2017. Jevtana® faces generic competition since September 2021 in the US and the end of March 2021 in Europe.

More generally, an expiration of effective intellectual property protections for our products typically results in the market entry of one or more lower-priced generic competitors, often leading to a rapid and significant decline in revenues on those products (for information regarding ongoing patent litigation see Note D.22.b.) to the consolidated financial statements included at Item 18. of this annual report).

The introduction of a generic product results in adverse price and volume effects for our branded or genericized products. For example, although we do not believe it is possible to state with certainty what level of net sales would have been achieved in the absence of generic competition, a comparison of our consolidated net sales for 2021 and 2020 for the main products affected by generic and biosimilar competition shows a loss of €231 million of net sales on a reported basis (see "Item 5. Operating and Financial Review and Prospects — A.1.2. Impacts of Competition from Generics and Biosimilars"). However, other parameters may have contributed to the loss of sales, such as a fall in the average price of certain products (e.g. Lantus®).

Furthermore, in general, if one or more of our flagship products were to encounter problems (such as material product liability litigation, unexpected side effects, product recalls, non-approval by the health authorities of a new indication for a marketed product, pricing pressure and manufacturing or supply issues), the adverse impact on our business, results of operations and financial condition could be significant.

We rely on third parties for the discovery, manufacture, marketing and distribution of some of our products

Our industry is both highly collaborative and competitive, whether in the discovery and development of new products, in-licensing, the marketing and distribution of approved products, or manufacturing activities. We expect that we will continue to rely on third parties for key aspects of our business and we need to ensure our attractiveness as a potential partner.

We conduct a number of significant research and development programs and market some of our products in collaboration with other biotechnology and pharmaceutical companies. For example, we currently have a global strategic collaboration with Regeneron on monoclonal antibodies for the development and commercialization of Dupixent®, Kevzara® (sarilumab) and SAR440340 (REGN3500-itepekimab). Further, in April 2020, Sanofi and Regeneron restructured their antibody collaboration related to Praluent® (alirocumab) (see "Item 5. Financial Presentation of Alliances — A.1.7.1/ Alliance Arrangements with Regeneron Pharmaceuticals Inc"). We rely upon Regeneron to successfully carry out their responsibilities with regard to the manufacture and supply of these collaboration antibodies. In immuno-oncology, we have a global collaboration with Regeneron for the joint development and commercialization of cemiplimab, a programmed cell death protein 1 (PD-1) inhibitor antibody (Libtayo®). (see "Item 4. Information on the Company — B. Business Overview"). Finally, we may also rely on partners to design and manufacture medical devices, notably for the administration of our products.

As regards products recently launched or under development for which we have a collaboration agreement with partners, the terms of the applicable alliance agreement may require us to share profits and losses arising from commercialization of such products with our partners. This differs from the treatment of revenue and costs generated by other products for which we have no alliance agreement, and such profit sharing may deliver a lower contribution to our financial results.

We could also be subject to the risk that we may not properly manage the decision-making process with our partners. Decisions may also be under the control of or subject to the approval of our collaboration partners, who may have views that differ from ours. We are also subject to the risk that our partners may not perform effectively, which could have a detrimental effect when our collaboration partners are responsible for the performance of certain key tasks or functions, for example related to manufacturing. Any such failures in the development process or differing priorities may adversely affect our business including the activities conducted through the collaboration arrangements We also cannot guarantee that third-party manufacturers will be able to meet our near-term or long-term manufacturing requirements. Subject to the completion of its initial public offering in the first half of 2022 including obtaining required market authority approvals, EUROAPI will also become a third-party manufacturer and will continue to manufacture a certain number of APIs for Sanofi. We are also subject to the risk that contract research organizations or other vendors (for instance regarding digital activities) retained by us or our collaboration partners may not perform effectively.

We could face conflicts or difficulties with these partners during the course of these agreements or at the time of their renewal or renegotiation. All of these events may affect the development, manufacturing, launch and/or marketing of certain of our products or product candidates and may cause a decline in our revenues or otherwise negatively affect our results of operations.

The extent to which the COVID-19 pandemic and related developments, including measures implemented in response thereto, may adversely impact our business, operations and financial performance is highly uncertain and difficult to predict

We are unable to predict the extent to which the rapidly changing pandemic and related developments, including the duration and long-term magnitude of the disruption, may adversely impact our business, operations and financial performance, including lower sales and reduced patient demand and usage of certain of our products.

While economies around the world have sought or will begin to seek to fully reopen their economies, the degree to which COVID-19 adversely impacts our results in the future is outside the Company's knowledge or control and will depend on future developments, including, but not limited to, the duration and spread of the outbreak, its mutation, its severity, the actions taken by government authorities to contain the virus or mitigate its impact, and how quickly and to what extent normal economic and operating conditions can resume. Any resurgence in COVID-19 infections could result in the imposition of new constraints and prolonged restrictive measures implemented in order to control the spread of the disease.

In an increasingly budget-constrained healthcare environment as economic disruption continues due to the pandemic, we expect to see a higher pressure on drug prices worldwide and, in the longer term, a reallocation of funding across therapeutic areas, driven in particular by evolving public health priorities, which could negatively impact our business operations (see "— The pricing and reimbursement of our products is increasingly affected by cost reduction initiatives and decisions of governments and other third parties" above). For example, the pandemic may reduce our sales in targeted markets due to lower healthcare spending on other diseases and fewer promotional activities.

If the pandemic is further prolonged, we may face delays in our clinical trials due to restrictions imposed on clinical trial sites and/or delays in the initiation and enrollment of patients in our clinical trials and/or disruptions related to regulatory approvals and/or delays in label expansions for existing products. We may not be able to fully mitigate these delays, which could negatively impact the timing of our pipeline development programs and may have a negative impact on our product development and launches and hence, on future product sales, business and results of operations.

The global COVID-19 pandemic also exposes us to a slowdown or temporary suspension in production of our active pharmaceutical ingredients (API), raw materials and some of our other products. Extension of the restrictive measures put in place in order to control the pandemic may lead to manufacturing delays or disruptions and supply chain interruptions (including to the extent those measures apply to our third-party suppliers) and may have an adverse effect on our business (see "— The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products and negatively impact our image" above). Also, a sudden increase in demand for selected medicinal products could result in short-term unavailability or shortages of raw materials.

In addition, it is not certain that we will successfully develop our vaccine for COVID-19 , nor that the vaccine candidate, if approved, would be commercially successful, nor that demand for such a vaccine or product would still exist. Post marketing clinical data and analysis of existing clinical data could also give rise to unexpected safety, quality or manufacturing issues.

In response to the COVID-19 pandemic, we have implemented proactive measures in order to protect our employees, including restricting employee travel and adopting a work-from-home policy. However, the pandemic could continue to pose risks to the health and safety of our employees, especially when employees may elect to return to the office in jurisdictions where both local requirements and our own health and safety standards have been met. Meanwhile, remote work could affect the employees engagement *vis-à-vis* Sanofi.

Finally, we cannot predict or reasonably estimate the impact of any potential long-term changes to the healthcare and pharmaceutical industries from the COVID-19 pandemic, and the volatile global economic conditions stemming from the pandemic, could precipitate or amplify the other risk factors that we identify in this "Risk Factors" section, which could adversely affect our business, operations and financial conditions and results. If the pandemic is further prolonged, our operations could also be adversely impacted by the work-from-home, lockdown and other restrictions that have been adopted in response to the pandemic. Any of these risks could cause actual results to differ materially from those described elsewhere in this report (see "Item 3.D. Risk Factors" and "— Global economic conditions and an unfavorable financial environment could have negative consequences for our business" below).

We are subject to the risk of non-payment by our customers[(1)]

We run the risk of delayed payments or even non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies. This risk is accentuated by recent concentrations among distributors and retailers, as well as by uncertainties around global credit and economic conditions, in particular in emerging markets. As a result, we may be affected by fluctuations in the buying patterns of such customers. The United States poses particular customer credit risk issues because of the concentrated distribution system: our three main customers represented respectively 10%, 7% and 6% of our consolidated net sales in 2021. We are also exposed to large wholesalers in other markets, particularly in Europe. An inability of one or more of these wholesalers to honor their debts to us could adversely affect our financial condition (see Note D.34. to our consolidated financial statements included at Item 18. of this annual report).

In some countries, some customers are public or subsidized health systems. The economic and credit conditions in these countries may lead to an increase in the average length of time needed to collect on accounts receivable or the ability to collect 100% of receivables outstanding. Because of this context, we may need to reassess the recoverable amount of our debts in these countries during future financial years.

Global economic conditions and an unfavorable financial environment could have negative consequences for our business[(2)]

Over the past several years, growth of the global pharmaceutical market has become increasingly tied to global economic growth. In this context, a substantial and lasting slowdown of the global economy, major national economies or emerging markets could negatively affect growth in the global pharmaceutical market and, as a result, adversely affect our business. For example, unpredictable political conditions that currently exist in various parts of the world could have a material negative impact on our business. Collectively, such unstable conditions could, among other things, disturb the international flow of goods and increase the costs and difficulties of international transactions.

Unfavorable economic conditions have reduced the sources of funding for national social security systems, leading to austerity measures including heightened pressure on drug prices, increased substitution of generic drugs, and the exclusion of certain products from formularies among others (see "— The pricing and reimbursement of our products is increasingly affected by cost containment pressures and decisions of governments and other third parties" above).

Further, our net sales may be negatively impacted by the continuing challenging global economic environment, as high unemployment, increases in cost-sharing, and lack of developed third-party payer systems in certain regions may lead some patients to switch to generic products, delay treatments, skip doses or use other treatments to reduce their costs. In the United States there has been a significant increase in the number of beneficiaries in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many US states, to formulary restrictions limiting access to brand-name drugs, including ours. Also, employers may seek to transfer a greater portion of healthcare costs to their employees due to rising costs, which could lead to further downward price pressure and/or lower demand.

Our Consumer Healthcare business could also be adversely impacted by difficult economic conditions that limit the financial resources of our customers.

If economic conditions worsen, or in the event of default or failure of major players including wholesalers or public sector buyers financed by insolvent states, our financial situation, the profitability and results of our operations and the distribution channels of our products may be adversely affected. See also "— We are subject to the risk of non-payment by our customers" above.

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(1) The information in this section supplements the disclosures required under IFRS 7 as presented in Notes B.8.7., D.10. and D.34. to our consolidated financial statements, provided at Item 18. of this annual report.

(2) The information in this section supplements the disclosures required under IFRS 7 as presented in Note B.8.7. to our consolidated financial statements, provided at Item 18. of this annual report.

The increasing use of social media platforms and new technologies present risks and challenges for our business and reputation

We increasingly rely on social media, new technologies and digital tools to communicate about our products and about diseases or to provide health services. The use of these media requires specific attention, monitoring programs and moderation of comments. Political and market pressures may be generated by social media because of rapid news cycles. This may result in commercial harm, overly restrictive regulatory actions and erratic share price performance. In addition, unauthorized communications, such as press releases or posts on social media, purported to be issued by Sanofi, may contain information that is false or otherwise damaging and could have an adverse impact on our image and reputation and on our stock price. Negative or inaccurate posts or comments about Sanofi, our business, directors or officers on any social networking website could seriously damage our reputation. In addition, our employees and partners may use social media and mobile technologies inappropriately, which may give rise to liability for Sanofi, or which could lead to breaches of data security, loss of trade secrets or other intellectual property or public disclosure of sensitive information. Such uses of social media and mobile technologies could have an adverse effect on our reputation, business, financial condition and results of operations.

Risks relating to Sanofi's structure and strategy

We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments or divestments

We pursue a strategy of selective acquisitions, in-licensing and collaborations in order to reinforce our pipeline and portfolio. We are also proceeding to selective divestments to focus on key business areas. The implementation of this strategy depends on our ability to identify transaction opportunities, mobilize the appropriate resources in order to enter into agreements in a timely manner, and execute these transactions on acceptable economic terms. Moreover, entering into in-licensing or collaboration agreements generally requires the payment of significant "milestones" well before the relevant products reach the market, without any assurance that such investments will ultimately become profitable in the long term (see Note D.21.1. to the consolidated financial statements included at Item 18. of this annual report and also "— We rely on third parties for the discovery, manufacture, marketing and distribution of some of our products" above).

For newly acquired activities or businesses, our growth objectives could be delayed or ultimately not realized, and expected synergies could be adversely impacted if, for example:

- we are unable to quickly or efficiently integrate those activities or businesses;
- key employees leave; or
- we have higher than anticipated integration costs.

For instance, in 2019 we had to book a €2.8 billion impairment on Eloctate®, acquired through the Bioverativ acquisition completed in 2018, due to revisions of previous sales projections. As another example, the Translate Bio acquisition referred to above which was completed in 2021 may not generate the expected results in terms of developing new mRNA-based products to meet existing or future needs, and the potential of Translate Bio's mRNA platform may not be realized to its full extent or because of the difficulty of integrating the activity quickly and efficiently into the Group.

We may also miscalculate the risks associated with business development transactions at the time they are made or may lack the resources or ability to access all the relevant information to evaluate such risks properly, including with regard to the potential of research and development pipelines, manufacturing issues, tax or accounting issues, compliance issues, or the outcome of ongoing legal and other proceedings. It may also take a considerable amount of time and be difficult to implement a risk analysis and risk mitigation plan after the acquisition of an activity or business is completed due to lack of historical data. Acquired businesses may not always be in full compliance with legal, regulatory or Sanofi standards, including, for example, current Good Manufacturing Practices (cGMP), which can be costly and time consuming to remedy. As a result, risk management and coverage of such risks, particularly through insurance policies, may prove to be insufficient or ill-adapted.

With respect to divestments, their financial benefit could be impacted if we face significant financial claims or significant post-closing price adjustments. Furthermore, the value of the assets to be divested may deteriorate while we are in the process of executing our divestment strategy, with the risk that we do not realize the anticipated benefits. For example, we announced in February 2020 a plan to create a future leading European company, now named EUROAPI, dedicated to the development, production and marketing of active pharmaceutical ingredients (API) to third parties as well as to Sanofi with a planned IPO on Euronext Paris in the first half of 2022, subject to market conditions and obtaining required market authority approvals. Given that market conditions can be volatile, we may not be able to realize the anticipated financial benefits of this transaction.

Because of the active competition among pharmaceutical groups for business development opportunities, there can be no assurance of our success in completing these transactions when such opportunities are identified.

The globalization of our business exposes us to increased risks in specific areas

As part of the presentation of our strategy in December 2019, we identified our strong presence in China among our core drivers, with revenue amounting to 7.2% of our net sales in 2021.

Nevertheless, the difficulties in operating in emerging markets, a significant decline in the anticipated growth rate or an unfavorable movement of the exchange rates of currencies against the euro could impair our ability to take advantage of growth opportunities and could adversely affect our business, results of operations or financial condition. For instance, while it continues to be impossible as of the date of this report to predict the economic impact and the magnitude of the ongoing COVID-19 pandemic, if a long-lasting epidemic and prolonged or repeated restrictive measures to control the outbreak were to result in an economic slowdown in any of our targeted markets, it would reduce our sales due to lower healthcare spending on other diseases and fewer promotional activities, and could significantly impact our business operations. Furthermore, it is not possible to predict if or how the current health crisis will impact any particular affected jurisdiction, or to what extent (see also "— Global economic conditions and an unfavorable financial environment could have

negative consequences for our business" and "The extent to which the COVID-19 pandemic and related developments, including measures implemented in response thereto, may impact our business, operations and financial performance is highly uncertain and difficult to predict" above).

Emerging markets also expose us to more volatile economic conditions, political instability (including a backlash in certain areas against free trade), competition from multinational or locally based companies that are already well established in these markets, the inability to adequately respond to the unique characteristics of emerging markets (particularly with respect to their underdeveloped judicial systems and regulatory frameworks), difficulties in recruiting qualified personnel or maintaining the necessary internal control systems, potential exchange controls, weaker intellectual property protection, higher crime levels (particularly with respect to counterfeit products), and compliance issues including corruption and fraud (see particularly "— Claims and investigations relating to ethics and business integrity, competition law, marketing practices, pricing, human rights of workers, data protection and other legal matters could adversely affect our business, results of operations and financial condition" above).

We may fail to develop or take advantage of digitalization

We have undertaken a number of digital initiatives (such as the opening in October 2019 of our Framingham digitally enabled manufacturing facility in the US, and our Darwin real-world data platform). Our success in these efforts will depend on many factors, including data quality, technology architecture, entering into successful partnerships and alliances with technology companies, a cultural change among our employees, attracting and retaining employees with appropriate skills and mindsets, and successfully innovating across a variety of technology fields. The COVID-19 pandemic has accelerated our digital transformation, including in the ways we engage and interact with our stakeholders. However, there is no guarantee that our efforts toward a digital transformation will succeed. More generally, we may fail to capture the benefits of digitalization at an appropriate cost and/or in a timely manner, and/or enter into appropriate partnerships. Competitors, including new entrants such as tech companies, may outpace us in this fast-moving area. If we fail to adequately integrate digitalization into our organization and business model, we could lose patients and market share. This could have an adverse impact on our business, prospects and results of operations.

We may fail to accelerate our operational efficiency

As part of our strategy, we announced our intent to improve our operating efficiencies to fund growth and expand our business operating income margin. We have also announced savings initiatives to fund investment in our key growth drivers, to accelerate priority pipeline projects and to support the expansion of our BOI margin. Nevertheless, there is no guarantee that we will be able to fully deliver these operating efficiencies within the targeted timeline or generate the expected benefits.

Unsuccessful management of environmental, social and governance matters could adversely affect our reputation and we may experience difficulties to meet the expectations of our stakeholders

Companies are increasingly expected to behave in a responsible manner on a variety of environmental, social and governance (ESG) matters, by governmental and regulatory authorities, counterparties such as vendors and suppliers, customers, investors, the public at large and others. This context, driven in part by a rapidly changing regulatory framework, is raising new challenges and influencing strategic decisions that companies must take if they wish to optimize their positive impact and mitigate their negative impact on ESG matters.

We have adopted an ESG strategy that aims at ensuring global access and affordability, addressing unmet needs with transformative therapies, and minimizing the impact of our activities and products on the climate and the environment. The strategy includes leveraging our personnel's experience and making societal impact a key driver of our employees' engagement. However, despite our strong commitment we could be unable to meet our ESG or other strategic objectives in an efficient and timely manner, or at all.

We may also be unable to meet the ever more demanding criteria used by rating agencies in their ESG assessments process, leading to a downgrading in our rating. Financial investments in companies which perform well in ESG assessments are increasingly popular, and major institutional investors have made known their interest in investing in such companies. Depending on ESG assessments and on the rapidly changing views on acceptable levels of action across a range of ESG topics from investors, we may be unable to meet society's or investors' expectations, our reputation may be harmed, we may face increased compliance or other costs and demand for securities issued by us and our ability to participate in the debt and equity markets may decrease.

Our success depends in part on our senior management team and other key employees and our ability to attract, integrate and retain key personnel and qualified individuals in the face of intense competition

Our success depends on the expertise of our senior management team and other key employees. In 2021, there were 2,346 "Senior Leaders" within Sanofi. In addition, we rely heavily on recruiting and retaining talented people to help us meet our strategic objectives. We face intense competition for qualified individuals for senior management positions, or in specific geographic regions or in specialized fields such as clinical development, biosciences and devices, or digital and artificial intelligence. Our ability to hire qualified personnel also depends in part on our ability to reward performance, incentivize our employees and pay competitive compensation. Laws and regulations on executive compensation may restrict our ability to attract, motivate and retain the required level of talented people. The inability to attract, integrate and/or retain highly skilled personnel, in particular those in leadership positions, may weaken our succession plans, may materially adversely affect the implementation of our strategy and our ability to meet our strategic objectives, and could ultimately adversely impact our business or results of operations.

Environmental and safety risks of our industrial activities

Risks from manufacturing activities and the handling of hazardous materials could adversely affect our results of operations

Manufacturing activities, such as the chemical manufacturing of the active ingredients in our products and the related storage and transportation of raw materials, products and waste, expose us to risks of industrial accidents that may lead to discharges or releases of toxic or pathogenic substances or other events that can cause personal injury, property damage and environmental contamination, and may result in additional operational constraints, including the shutdown of affected facilities and/or the imposition of civil, administrative, criminal penalties and/or civil damages.

The occurrence of an industrial accident may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results and reputation. Although we maintain property damage, business interruption and casualty insurance that we believe is in accordance with customary industry practices, this insurance may not be adequate to fully cover all potential hazards incidental to our business.

Management of the historical contamination related to our past industrial activities may have a significant adverse effect on our results of operations

The environmental laws of various jurisdictions impose actual and potential obligations on our Company to manage and/or remediate contaminated sites. These obligations may relate to sites:

- that we currently own or operate;
- that we formerly owned or operated; or
- where waste from our operations was disposed.

These environmental remediation obligations could reduce our operating results. Sanofi accrues provisions for remediation when our management believes the need is probable and that it is reasonably possible to estimate the cost. See “Item 4. Information on the Company — B. Business Overview — B.10. Health, Safety and Environment” for additional information regarding our environmental policies. In particular, our provisions for these obligations may be insufficient if the assumptions underlying these provisions prove incorrect or if we are held responsible for additional, currently undiscovered contamination. These judgments and estimates may later prove inaccurate, and any shortfalls could have an adverse effect on our results of operations and financial condition. For more detailed information on environmental issues, see “Item 4. Information on the Company — B. Business Overview — B.10. Health, Safety and Environment and Notes B.12. and D.19.3. to the consolidated financial statements”.

We are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former Sanofi subsidiaries have been named as “potentially responsible parties” or the equivalent under the US Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (also known as “Superfund”), and similar statutes or obligations in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligations, we and/or our subsidiaries may retain responsibility for environmental liabilities at some of the sites of our predecessor companies, or of subsidiaries that we demerged, divested or may divest. We have disputes outstanding regarding certain sites no longer owned or operated by the Company. An adverse outcome in such disputes might have an adverse effect on our operating results. See Note D.22.d) to the consolidated financial statements included at Item 18. of this annual report and “Item 8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings”.

Environmental regulations are evolving. For example, in Europe, new or evolving regulatory regimes include REACH, CLP/GHS, SEVESO, IPPC/IED, the Waste Framework Directive, the Emission Trading Scheme Directive, the Water Framework Directive, the Directive on Taxation of Energy Products and Electricity and several other regulations aimed at preventing climate change. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to our Company and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants, site restoration and compliance to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, results of operations or financial condition.

Risks related to financial markets[(3)]

Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition

Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the US dollar, the Japanese yen, the Chinese yuan, and currencies in emerging markets. In 2021, 38.1% of our net sales were generated in the United States, 25.8% in Europe, and 36.1% in the Rest of the World region (see the definition in “Item 5. Operating and Financial Review and Prospects — A/ Operating results”), including countries that are, or may in future become, subject to exchange controls (including 7.2% in China and 4.4% in Japan). While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations or financial condition. For more information concerning our exchange rate exposure, see “Item 11. Quantitative and Qualitative Disclosures about Market Risk”.

[(3)] *The information in this section supplements the disclosures required under IFRS 7 as presented in Note B.8.7. to our consolidated financial statements, provided at Item 18. of this annual report.*

Risks relating to an investment in our shares or ADSs

Foreign exchange fluctuations may adversely affect the US dollar value of our ADSs and dividends (if any)

Holders of ADSs face exchange rate risk. Our ADSs trade in US dollars and our shares trade in euros. The value of the ADSs and our shares could fluctuate as the exchange rates between these currencies fluctuate. If and when we pay dividends, they would be denominated in euros. Fluctuations in the exchange rate between the euro and the US dollar will affect the US dollar amounts received by owners of ADSs upon conversion by the depositary of cash dividends, if any. Moreover, these fluctuations may affect the US dollar price of the ADSs on the NASDAQ Global Select Market (NASDAQ) whether or not we pay dividends, in addition to any amounts that a holder would receive upon our liquidation or in the event of a sale of assets, merger, tender offer or similar transaction denominated in euros or any foreign currency other than US dollars.

Persons holding ADSs rather than shares may have difficulty exercising certain rights as a shareholder

Holders of ADSs may have more difficulty exercising their rights as a shareholder than if they directly held shares. For example, if we issue new shares and existing shareholders have the right to subscribe for a pro rata portion of the new issuance, the depositary is allowed, at its own discretion, to sell this right to subscribe for new shares for the benefit of the ADS holders instead of making that right available to such holders. In that case, ADS holders could be substantially diluted. Holders of ADSs must also instruct the depositary how to vote their shares. Because of this additional procedural step involving the depositary, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting. US investors may have difficulty in serving process or enforcing a judgment against us or our directors or executive officers.

Sales of our shares may cause the market price of our shares or ADSs to decline

Sales of large numbers of our shares, or a perception that such sales may occur, could adversely affect the market price for our shares and ADSs. To our knowledge, L'Oréal, our largest shareholder, is not subject to any contractual restrictions on the sale of the shares it holds in our Company. L'Oréal does not consider its stake in our Company as strategic.

Our largest shareholder owns a significant percentage of the share capital and voting rights of Sanofi

As of December 31, 2021, L'Oréal held approximately 9.36% of our issued share capital, accounting for approximately 16.78% of the voting rights (excluding treasury shares) of Sanofi. See "Item 7. Major Shareholders and Related Party Transactions — A. Major Shareholders". Affiliates of L'Oréal currently serve on our Board of Directors. To the extent L'Oréal continues to hold a large percentage of our share capital and voting rights, it will remain in a position to exert greater influence in the appointment of the directors and officers of Sanofi and in other corporate actions that require shareholders' approval.

Item 4. Information on the Company

Introduction

Sanofi is a leading global healthcare company, focused on patient needs and engaged in the research, development, manufacture and marketing of therapeutic solutions.

In the remainder of this section, a product is referred to either by its international non-proprietary name (INN) or its brand name, which is generally exclusive to the company that markets it. In most cases, the brand names of our products, which may vary from country to country, are protected by specific registrations. In this document, products are identified by their brand names used in France and/or in the US.

Sanofi has three principal activities: Pharmaceuticals, Consumer Healthcare, and Vaccines. These activities are operating segments within the meaning of the IFRS 8 accounting standard (see Note D.35. to our consolidated financial statements, included at Item 18. of this annual report). Our activities comprise: Dupixent®; Neurology & Immunology; Rare Diseases; Oncology; Rare Blood Disorders; Diabetes; Cardiovascular and Established Prescription Products; Consumer Healthcare; and Vaccines. Unlike our Vaccines and Consumer Healthcare activities, which are also operating segments within the meaning of IFRS 8, our Pharmaceuticals activities are franchises whose performance is monitored primarily on the basis of net sales; the products sold by each of those franchises are included in our Pharmaceuticals operating segment. For a presentation of the net sales of our activities for the year ended December 31, 2021, refer to "Item 5. — Results of Operations — Year Ended December 31, 2021 Compared with Year Ended December 31, 2020".

In 2021, Sanofi obtained regulatory marketing approval for a number of products. In the United States, the PD-1 inhibitor **Libtayo®** (cemiplimab-rwlc) received full approval for locally advanced basal cell carcinoma (BCC) and accelerated approval in metastatic BCC, following a priority review by the US Food and Drug Administration (FDA). Libtayo® is now approved for the two most common advanced skin cancers in the United States. The European Commission also approved Libtayo® for the treatment of metastatic or locally advanced BCC in adults. The FDA and the European Commission approved Libtayo® for the first-line treatment of patients with advanced non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression. The FDA and the European Commission approved **Sarclisa®** (isatuximab-irfc), in combination with carfilzomib and dexamethasone, for adult patients with relapsed and refractory multiple myeloma who have received one to three prior therapies. The European Commission approved **Aubagio®** (teriflunomide) for the treatment of pediatric patients aged 10 to 17 years with relapsing-remitting multiple sclerosis (MS). The approval confirms Aubagio® as the first oral therapy for first-line treatment of children and adolescents with MS in the European Union. The FDA approved **Nexviazyme®** (avalglucosidase alfa-ngpt) for the treatment of patients one year of age and older with late-onset Pompe disease, a progressive and debilitating muscle disorder that impairs a person's ability to move and breathe. The FDA also approved **Dupixent®** (dupilumab) as an add-on maintenance treatment of patients aged 6 to 11 years with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid-dependent asthma. In China, **Dupixent®** was approved for the treatment of atopic dermatitis in adolescents aged 12 to 17 years.

Collaborations are essential to our business and a certain number of our products, whether on the market or under development, are in-licensed products relying on third-party rights or technologies.

A. History and development of the Company

The current Sanofi corporation was incorporated under the laws of France in 1994 as a *société anonyme*, a form of limited liability company, for a term of 99 years. Since May 2011, we have operated under the commercial name "Sanofi" (formerly known as Sanofi-Aventis). Our registered office is located at 54, rue La Boétie, 75008 Paris, France, our main telephone number is +33 1 53 77 40 00 and our website is www.sanofi.com. Our principal US subsidiary's office is located at 55 Corporate Drive, Bridgewater, NJ 08807; telephone: +1 (908) 981 5000.

The SEC maintains an internet site at http://www.sec.gov that contains reports, information statements, and other information regarding issuers that file electronically with the SEC.

Main changes over the last five years

On January 1, 2017, Sanofi and Boehringer Ingelheim (BI) successfully closed in most markets a transaction to swap Sanofi's Animal Health business for BI's CHC business.

On March 8, 2018, following a tender offer, we acquired control of Bioverativ Inc., a US biopharmaceutical company headquartered in Waltham, Massachusetts, engaged in the development of therapies for people with hemophilia and other rare blood disorders.

On June 19, 2018, Sanofi finalized the acquisition of Ablynx, a Belgian biopharmaceutical company engaged in the development of Nanobodies® – which combine the advantages of conventional antibody drugs with some of the features of small-molecule drugs – in various therapeutic areas.

On September 30, 2018, we completed the divestment of our European generics business Zentiva to Advent International, a US global private equity firm.

On January 23, 2020, following a tender offer, we acquired control of Synthorx, a US clinical-stage biotechnology company based in La Jolla, California, focused on prolonging and improving the lives of people suffering from cancer and autoimmune disorders.

On September 28, 2020, we completed the acquisition of Principia Biopharma Inc., a late-stage biopharmaceutical company focused on developing treatments for autoimmune diseases.

On April 8, 2021, Sanofi acquired the entire share capital of Kymab, a clinical-stage biopharmaceutical company developing fully human monoclonal antibodies with a focus on immune-mediated diseases and immuno-oncology therapeutics.

On September 14, 2021, Sanofi finalized the acquisition of Translate Bio, a clinical-stage mRNA therapeutics company.

On November 9, 2021, Sanofi completed the acquisition of Kadmon Holdings, Inc. a biopharmaceutical company that discovers, develops, and markets transformative therapies for disease areas of significant unmet medical need.

B. Business overview

B.1. Strategy

The market context for Sanofi

A number of fundamental trends continue to point to a positive outlook for the pharmaceutical industry. The global population is growing, and aging, and unmet medical needs remain high. With the COVID-19 pandemic, health needs have further increased, strengthening the key roles of innovation in R&D activities and cutting-edge manufacturing. The industry has taken steps to increase R&D productivity, with the objective of launching a higher number of innovative medicines and vaccines. Patients around the world – including a rising middle class in emerging markets – are demanding better healthcare, empowered by access to more and more information. It is a particularly exciting time scientifically and technologically: the promise of genomics is being realized, immuno-oncology is transforming cancer treatments, and big data is generating new insights into how to diagnose and treat diseases. Digital technologies and advanced data analytics are having a transformative effect across sales and marketing activities, R&D and manufacturing, and are acting as enablers for new businesses.

At the same time, increased geopolitical uncertainties, the economic crisis linked to the COVID-19 pandemic, and issues around budget tightening will continue to put pressure on healthcare costs, and on the entire healthcare value chain. Although we believe that pharmaceuticals and vaccines will remain a fundamentally attractive business within that value chain, the bar for innovation will most likely continue to rise. Payers will continue to put scrutiny on prices and reimbursement criteria, and demand demonstration of real-life outcomes to confirm the efficacy of medicines and vaccines. This will be coupled with more innovative pricing and contracting practices, and more transparent policies. In view of growing concerns over increasing healthcare costs across global markets, the pharmaceutical industry will be increasingly judged by its contribution to improved access for patients and to the development of innovative, highly cost-effective medicines.

Strategic framework

The Sanofi “Play to Win” strategy is organized around four key priorities: (1) focus on growth; (2) lead with innovation; (3) accelerate efficiency; and (4) reinvent how we work to drive innovation and growth.

1) Focus on growth

- **Dupixent® (dupilumab)[1]** – By leveraging the product's unique mechanism of action targeting the type 2 inflammation pathway and its favorable safety profile, Sanofi is maximizing the value of Dupixent® in multiple indications, with the ambition for the product to deliver strong growth to over €10 billion in annual net sales.
- **Vaccines** – Our Vaccines business is expected to deliver mid-to-high single digit net sales growth[2] through differentiated products, market expansions and launches. Contributors to growth are expected to be pediatric combinations, boosters, influenza vaccines, meningitis and the launch of nirsevimab, a monoclonal antibody addressing Respiratory Syncytial Virus (RSV)[3]. Sanofi has progressed in the field of mRNA technology with the recently established Center of Excellence and the integration of Translate Bio. Of the 10 new vaccine candidates planned to enter the clinic by 2025, six will use mRNA technologies to target diseases with high unmet needs and disease burden such as chlamydia and acne. The long-term ambition is to more than double Vaccines sales by the end of the decade based on 2018 sales.
- **Pipeline** – We are focusing our investments on priority projects, including six potentially transformative therapies in oncology, immunology, hematology, neurology,and vaccines.

2) Lead with innovation

Sanofi has prioritized six potentially practice-changing assets in areas of high unmet patient need. These investigational therapies are listed below:

- **Amcenestrant** is an oral selective estrogen receptor degrader, which aims to be the new standard of care in hormone-receptor-positive breast cancer;
- **Fitusiran** is a small interference RNA therapeutic in development for the treatment of hemophilia A and B with or without inhibitors, with the potential to be a first-in-class therapeutic option;
- **Efanesoctocog alfa[4]** is a new class of factor therapy engineered to achieve higher factor levels with the potential to deliver unprecedented protection for people with hemophilia A, allowing them to achieve near-normal factor activity with a once-weekly dose;
- **Amlitelimab**, a non-depleting aOX40Ligand monocloncal antibody has the potential to bebest-in-class treatment for a range of immune-mediated diseases and inflammatory disorders, including moderate-to-severe atopic dermatitis. By targeting OX40-Ligand, amlitelimab aims to restore immune homeostasis between pro-inflammatory and anti-inflammatory T cells;

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[1] In partnership with Regeneron.
[2] Cumulative Annual Growth Rate (CAGR), 2018-2025.
[3] In partnered with AstraZeneca.
[4] In partnership with Swedish Orphan Biovitrum (Sobi).

- **Nirsevimab**[(5)], a monoclonal antibody, is a potentially cost-effective prevention against respiratory syncytial virus (RSV), for all infants. Its high affinity to RSV could potentially allow a single injection to cover for the entire RSV season;
- **Tolebrutinib** is an oral selective, brain penetrant BTK inhibitor with the potential to be the first disease-modifier to address sources of multiple sclerosis damage in the brain.

To continue fueling our promising pipeline and enhance our position as an emerging leader in the area of oncology and immunology, we have:

i. entered into a licensing agreement with Biond Biologics with respect to BND-22, a novel immune checkpoint inhibitor targeting the ILT2 receptor;

ii. signed an exclusive worldwide licensing agreement with C4X with respect to the C4XD oral IL-17A inhibitor program;

iii. entered into a new license agreement with Eureka Therapeutics, Inc. on GPRC5D, targeting multiple myeloma;

iv. committed to invest in equity in Gyroscope Therapeutics Holdings plc to further validate the potential of the GT005 investigational gene therapy in geographic atrophy and support the ongoing Phase II development program;

v. invested $180 million of equity in Owkin's artificial intelligence and federated learning to advance our oncology pipeline;

vi. established a strategic research collaboration and license agreement with Exscientia to develop up to 15 novel small molecule candidates across oncology and immunology, leveraging Exscientia's end-to-end AI-driven platform utilizing actual patient samples;

vii. acquired Kymab Group Ltd.;

viii. acquired Kiadis Pharma N.V.;

ix. acquired Tidal Therapeutics, a privately owned, pre-clinical stage biotech company with a novel mRNA-based approach for in vivo reprogramming of immune cells;

x. completed the acquisition of Translate Bio, further accelerating our efforts to develop transformative vaccines and therapies using mRNA technology;

xi. acquired Origimm Biotechnology GmbH, a company with an innovative program to treat acne with vaccine-based immunotherapy; and

xii. entered into an agreement to acquire Amunix Pharmaceuticals, Inc., an immuno-oncology company leveraging its proprietary, clinically validated XTEN® and innovative universal protease-releasable masking technology platform, Pro-XTEN™, to discover and develop transformative T-cell engagers (TCE) and cytokine therapies for patients with cancer. This acquisition supports Sanofi's efforts to accelerate and expand our contributions to innovative medicines for oncology patients.

To further grow our transplant business, we have acquired Kadmon Holdings, Inc., a biopharmaceutical company that discovers, develops, and markets transformative therapies for disease areas of significant unmet medical need. The acquisition supports our strategy of continuing to grow our General Medicines core assets, and immediately add Rezurock™ (belumosudil) to our transplant portfolio. Rezurock™ is a recently US FDA-approved, first-in-class treatment for chronic graft-versus-host disease (cGVHD) for adult and pediatric patients aged 12 years and older who have failed at least two prior lines of systemic therapy.

Taking into account public health needs and the expectation that there will be sufficient mRNA COVID-19 vaccine supply going forward, Sanofi has decided not to pursue the development of its COVID-19 mRNA candidate into a Phase III clinical study and will focus on completing the final development steps of its COVID-19 recombinant vaccine, developed in partnership with GlaxoSmithKline (GSK).

Building on its positive results, Sanofi will focus its mRNA resources on its newly created mRNA Center of Excellence to address other infectious diseases where there is a strong unmet need.

3) Accelerate efficiency

We aim to increase our business operating income (BOI) margin through efficiency initiatives, and we expect to generate €2.5 billion of savings by end of 2022. These savings will fund investments in growth drivers, as well as supporting an increase of our BOI margin. In 2021, we achieved around €730 million of savings from (i) limiting spend on de-prioritized businesses; (ii) smart spending initiatives in procurement; and (iii) operational excellence in manufacturing and organizational productivity.

In order to better adapt our industrial capability to our evolving manufacturing needs, we announced in February 2020 a plan to create a leading European company, now named EUROAPI, dedicated to the developement, production and marketing of active pharmaceutical ingredients (API) to third parties as well as to Sanofi. The project involves creating a standalone company which combines Sanofi's API commercial and development activities from six of our European API production sites. The new company is estimated to rank as the world's second largest API manufacturing company, with approximately €1 billion in sales. The carve-out was finalized in December 2021. An IPO on Euronext Paris is envisaged in the first half of 2022, subject to market conditions and obtaining required market authority approvals.

To embrace the transformative effect offered by digital technologies and advanced data analytics, we are investing to become the leading digital healthcare platform for employees, patients and providers. This will help us discover, test and deliver medicines faster, run our business more efficiently, and create engaging digital experiences. The digital transformation required to meet our ambition is under way. We are using advanced algorithms to harvest real world data to support our R&D efforts. We are also developing new go-to-market models by closer physician engagement through a variety of channels, building precision marketing, and providing better e-commerce capabilities. And in parallel, we are investigating the possibility of integrating drugs, devices, data and services, to bring innovative solutions to patients across many different disease areas such as diabetes and atopic dermatitis.

(5) *In partnered with AstraZeneca.*

4) Reinvent how we work

Transformation and simplification have started, with the aim of increasing empowerment and accountability. To drive implementation of our new culture built on stronger focus, diversity and teamwork, we have streamlined our executive leadership team from fifteen to ten members. Two new members were appointed to the executive leadership team: Brendan O'Callaghan as Global Head of Industrial Affairs in October 2021 (succeeding Philippe Luscan) and Roy Papatheodorou as General Counsel and Head of Legal, Ethics & Business Integrity in February 2022 (succeeding Karen Linehan). The complete Sanofi Executive Committee now includes the four managers who head up our global business units (Sanofi Genzyme, Sanofi Pasteur, General Medicines, and Consumer Healthcare) as well as the heads of each of the following support functions: Research and Development, Industrial Affairs, Finance, Human Resources, Legal and Digital.

The creation of our standalone Consumer Healthcare business unit has progressed in 2021. By year end, we had set up the majority of the legal entities relating to this standalone business, with integrated R&D and manufacturing functions plus dedicated support functions and information technology. We believe this is a unique opportunity to adapt our business model specifically to the needs of the Consumer Healthcare sector, helping us to gain in agility as well as to accelerate our digital transformation.

Sanofi's integrated social impact strategy aims to build a healthier, more resilient world by contributing access to healthcare for the world's poorest people and bringing focus to addressing broader unmet needs, an approach that is built onto our "Play to Win" business strategy. We will continue the fight against infectious diseases such as sleeping sickness and poliomyelitis, while accelerating our goals to reduce the environmental impact of our products and of our worldwide operations. Key to tackling the global challenges that face society are our people, who each have a role to play in building a diverse and inclusive workplace.

Sanofi's Social Impact Strategy focuses on four building blocks aligned with our Play to Win core business strategy:

- affordable access – to ensure affordable global access to health, while helping healthcare systems to remain sustainable;
- R&D for unmet medical needs – to be at the cutting edge of R&D innovation, to help people live fully and drive growth;
- efficiency & sustainability – to minimize the environmental impact of our business through environmental sustainability; and
- beyond the workplace – to give all Sanofi colleagues the chance to become a leader of change, unlocking the potential of our diverse teams.

With this new policy, Sanofi aims to extend its "Play to Win" commitment to society.

Capital allocation policy

We will continue to pursue our focused and disciplined capital allocation policy. Our priorities in deploying the cash generated from our three core GBUs and the standalone CHC business are, in the following order: (i) organic investment; (ii) business development and merger & acquisition activities, focusing on bolt-on, value-enhancing opportunities to drive scientific and commercial leadership in core therapeutic areas; (iii) growing the annual dividend; and (iv) anti-dilutive share buybacks. We also have the potential to raise capital through asset disposals, including streamlining "tail" brands in our Established Products and Consumer Healthcare business.

B.2. Main pharmaceutical products

The sections below provide additional information on our main products. Our intellectual property rights over our pharmaceutical products are material to our operations and are described at "B.7. Patents, Intellectual Property and Other Rights" below. As disclosed in "8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Patents" of this annual report, we are involved in significant litigation concerning the patent protection of a number of these products. For more information on sales performance, see "Item 5. Operating and Financial Review and Prospects — Results of Operations".

Specialty Care

Dupixent®

Dupixent® (dupilumab), a human monoclonal antibody, binds to the interleukin-4 receptor alpha (IL-4Ra) and has been shown to specifically inhibit overactive signaling of two key proteins (IL-4 and IL-13), which are believed to be major drivers of multiple inflammatory diseases with underlying type 2 signatures, such as atopic dermatitis (AD) and asthma. Dupixent® comes in either a pre-filled syringe for use in a clinic or at home by self-administration as a subcutaneous injection or in a pre-filled pen for at-home administration, providing patients with a more convenient option. Dupixent® is available in all major markets including the US (since April 2017), most European Union countries (the first launch was in Germany in December 2017), and Japan (since April 2018).

Atopic Dermatitis (AD)

Moderate-to-severe atopic dermatitis, a form of eczema and a chronic inflammatory disease, is characterized by rashes that sometimes cover much of the body and can include intense, persistent itching and skin dryness, cracking, redness, crusting and oozing.

Dupixent® was granted marketing authorization by the FDA in March 2017 for the treatment of adults with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. In March 2019, the FDA extended the marketing authorization for adolescent patients aged 12 to 17 years. The FDA previously granted Breakthrough Therapy designation to Dupixent® for the treatment of severe atopic dermatitis in children aged 6 months to 11 years not well controlled on topical prescription medications. On March 26, 2020, the FDA approved Dupixent® as the first biologic medicine for children aged 6 to 11 years with moderate-to-severe AD.

On August 30, 2021, the Phase III pivotal trial met all primary and secondary endpoints, making Dupixent® the first biologic medicine to significantly reduce signs and symptoms of moderate-to-severe atopic dermatitis in children as young as 6 months after the first dose, improving itch in one week and skin clearance in two weeks. These results reinforce the well-established safety profile of Dupixent®.

On September 28, 2021, we announced results from new analyses in patients as young as 6 years old with moderate-to-severe atopic dermatitis, and results from long-term treatment (up to 3½ years) for adults in the same indication – the longest treatment with a biologic medicine ever administered to patients. The new data built on the existing wealth of evidence supporting the selective way Dupixent® specifically targets the underlying type 2 inflammation via targeting IL4/IL-13 that contributes to diseases like atopic dermatitis, significantly improving itch and skin lesions and other important measures that impact a patient's quality of life.

The European Commission (EC) approved Dupixent® in September 2017 for use in adults with moderate-to-severe AD who are candidates for systemic therapy,and extended the marketing authorization in August 2019 to include adolescents aged 12 to 17 years. On November 30, 2020, the EC extended the marketing authorization to children aged 6 to 11 years with severe AD and on June 28, 2021 the Dupixent® Summary of Product Characteristics (SmPC) was updated with long-term data following a positive opinion issued by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) reinforcing the product's well-established safety profile in adults with moderate-to-severe atopic dermatitis.

On June 19, 2020, the National Medical Products Administration (NMPA) in China approved Dupixent® for the treatment of moderate-to-severe AD after identifying dupilumab as an overseas medicine regarded as urgently needed in clinical practice, leading to an expedited review and approval process. On December 28, 2020, the National Healthcare Security Administration (NHSA) officially announced the results of the 2020 National Reimbursement Drug List (NRDL) negotiations, with Dupixent® 300 mg included in the updated NRDL effective March 1, 2021. Dupixent® was approved in China in September 2021 for adolescents aged 12-17 years with moderate-to-severe atopic dermatitis.

Asthma

Dupixent® was granted marketing authorization by the FDA in October 2018 as an add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma. In May 2019, the European Commission approved Dupixent® for use as an add-on maintenance treatment in severe asthma patients aged 12 years and older with type 2 inflammation who are inadequately controlled with high dose inhaled corticosteroid plus another medicinal product for maintenance treatment.

In September 2020, new long-term data from a Phase III open-label extension trial showed sustained improvement in lung function and reduction in severe exacerbations in adults and adolescents with moderate-to-severe asthma. On May 17, 2021, detailed results from a Phase III trial showed Dupixent® significantly reduced severe asthma attacks, and within two weeks rapidly improved lung function in children aged 6 to 11 years with uncontrolled moderate-to-severe asthma with evidence of type 2 inflammation. Moreover, Dupixent® significantly improved overall asthma symptom control and reduced an airway biomarker of type 2 inflammation, called fractional exhaled nitric oxide (FeNO), that plays a major role in asthma. On October 2021, the FDA approved Dupixent® as an add-on maintenance treatment for patients aged 6 to 11 years with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid-dependent asthma, thereby bringing a new treatment for children who may be suffering from life-threatening asthma attacks and poor lung function affecting their ability to breathe, which could potentially continue into adulthood.

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

CRSwNP is a chronic disease of the upper airway that obstructs the sinuses and nasal passages. It can lead to breathing difficulties, nasal congestion and discharge, reduced or loss of sense of smell and taste, and facial pressure.

In June 2019, the FDA approved Dupixent® for use with other medicines to treat CRSwNP in adults whose disease is not controlled. In October 2019, the European Commission approved Dupixent® for use as an add-on therapy with intranasal corticosteroids in adults with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

Eosinophilic esophagitis (EoE)

EoE is a chronic and progressive type 2 inflammatory disease that damages the esophagus and prevents it from working properly, leading to difficulties swallowing. There are currently no FDA-approved medicines for EoE. Dupixent® was granted Orphan Drug designation for the potential treatment of EoE in 2017. In May 2020, we announced positive results from Study A of the pivotal Phase III program evaluating Dupixent® in patients aged 12 years and older with EoE. The trial met both of its co-primary endpoints, as well as all key secondary endpoints. In September 2020, the FDA granted Breakthrough Therapy designation to Dupixent® for the treatment of patients aged 12 years and older with EoE. In October 2020, additional positive results were announced from Study A showing significant improvement in disease severity and extent, as well as normalized gene expression associated with type 2 inflammation. On October 25, 2021, Study B of the pivotal Phase III program showed positive results in patients 12 years and older with EoE meeting co-primary endpoints in patients taking Dupixent® 300 mg weekly, and showing significant improvements in clinical (Dysphagia Symptom Questionnaire) and histologic disease measures compared to a placebo. Dupixent® is the first and only biologic to show positive and clinically-meaningful results in this population as part of a Phase III program. The clinical trial program is ongoing, with patients from the first and second trials continuing into a 28-week long-term extension trial (Part C). Full results from this trial will be available in 2022.

Chronic Spontaneous Urticaria (CSU)

CSU is a chronic inflammatory skin disease characterized by the sudden onset of hives on the skin and/or swelling deep under the skin. Despite standard-of-care treatment, people with CSU often experience symptoms including a persistent itch or burning sensation, which can be debilitating and significantly impact quality of life. Swelling often occurs on the face, hands and feet, but can also affect the throat and upper airways. On July 29, 2021 a pivotal Phase III trial evaluating Dupixent® in patients with moderate-to-severe CSU met its primary endpoints and all key secondary endpoints at 24 weeks. Adding Dupixent® to standard-of-care antihistamines significantly reduced itch and hives for biologic-naive patients, compared to those treated with antihistamines alone (placebo) in Study A (the first of two trials) of the LIBERTY CUPID clinical program.

Study B of the clinical trial evaluates Dupixent® in adults and adolescents who remain symptomatic despite standard-of-care treatment and are intolerant or incomplete responders to an anti-IgE therapeutic (omalizumab). Although positive numerical trends in reducing itch and hives were observed, the results from the interim analysis did not demonstrate statistical significance for the primary endpoints. The safety

data were generally consistent with the known safety profile of Dupixent® in its approved indications. Sanofi and Regeneron remain committed to advancing Dupixent® for patients with CSU uncontrolled on antihistamines and are evaluating next steps.

Prurigo Nodularis (PN)

People with prurigo nodularis experience intense, persistent itch, with thick skin lesions (called nodules) that can cover most of the body. It is often described as painful with burning, stinging and tingling of the skin. There are no approved systemic treatments for prurigo nodularis. On October 22, 2021 a pivotal Phase III trial evaluating Dupixent® in adults with uncontrolled prurigo nodularis met its primary and all key secondary endpoints, showing that Dupixent® significantly reduced itch at 12 weeks and skin lesions at 24 weeks compared to placebo in this investigational setting. The impact of uncontrolled prurigo nodularis on quality of life is one of the highest among inflammatory skin diseases with intense, chronic itch. Prurigo nodularis is the sixth disease in which Dupixent® has entered a Phase III trial, reinforcing its well-established safety profile. Positive top-line data have been announced for the replicate Phase III studies in the LIBERTY-PN clinical program: PRIME2 (in October 2021) and PRIME (in January 2022). Sanofi and Regeneron plan to begin regulatory submissions in 2022.

Dupixent® is currently being evaluated in clinical development programs for diseases that are driven by type 2 inflammation. These include chronic obstructive pulmonary disease (COPD), bullous pemphigoid (BP), chronic inducible cold urticaria (CINDU) chronic rhinosinusitis without nasal polyposis (CRSsNP), and allergic fungal rhinosinusitis (AFRS). See "— B.5. Global Research & Development".

Dupixent® is developed and commercialized in collaboration with Regeneron. For additional information on the collaboration, see "Item 5. Operating and Financial Review and Prospects — Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

There are ongoing opposition proceedings in Europe related to Dupixent® initiated by Sanofi and Regeneron against Amgen and Immunex. See Note D.22.b.) to the consolidated financial statements included at Item 18. of this annual report.

Neurology & Immunology

Multiple Sclerosis

Multiple sclerosis (MS) is an autoimmune neurological disease in which a person's immune system attacks the central nervous system, damaging myelin, the protective sheath that covers nerve fibers. This causes a break in communication between the brain and the rest of the body, ultimately destroying the nerves themselves, and causing irreversible damage. More than 2.5 million people suffer from MS worldwide.

Our MS franchise consists of Aubagio® (teriflunomide), a once-daily, oral immunomodulator, and Lemtrada® (alemtuzumab), a monoclonal antibody. Both products treat patients with relapsing forms of MS.

Aubagio®

Aubagio® (teriflunomide), a small molecule immunomodulatory agent with anti-inflammatory properties, is a once-daily oral therapy.

Aubagio® is approved in more than 80 countries around the world including the US (since September 2012) for the treatment of patients with relapsing forms of MS; the EU (since August 2013) for the treatment of adult patients with relapsing remitting MS; and China (since July 2018). In June 2021, the European Commission (EC) approved Aubagio® for the treatment of pediatric patients aged 10 to 17 years with relapsing-remitting multiple sclerosis (RRMS). The EC approval of the pediatric indication provides Aubagio® with an additional year of marketing protection in the European Union.

In 2017, Sanofi reached settlement with all 20 generic Aubagio® ANDA first filers, granting each a royalty-free license to enter the US market on March 12, 2023.

Lemtrada®

Lemtrada® (alemtuzumab) is a humanized monoclonal antibody targeting the CD52 antigen. Lemtrada® is administered by intravenous infusion as two short courses 12 months apart; for the majority of patients no further treatment is necessary, making Lemtrada® the only disease-modifying therapy (DMT) that can provide long term durable efficacy in the absence of continuous dosing.

Lemtrada® is approved in more than 70 countries including the EU (since September 2013) and the US (since November 2014). Because of its safety profile, the FDA approved the use of Lemtrada® in patients with relapsing forms of MS who have had an inadequate response to two or more drugs indicated for the treatment of MS, and included a black-box warning on potential side effects. In the US, Lemtrada® is only available through a restricted distribution program called the Lemtrada® Risk Evaluation and Mitigation Strategy (REMS) Program. In January 2020, the EMA updated the indication for Lemtrada® to include treatment of relapsing-remitting multiple sclerosis if the disease is highly active despite treatment with at least one disease-modifying therapy, or if the disease is worsening rapidly. The EMA also added new contra-indications for patients with certain heart, circulation or bleeding disorders, and those who have autoimmune disorders other than MS.

Bayer Healthcare receives contingent payments based on alemtuzumab global sales revenue. For additional information, see Note D.18. to our consolidated financial statements, included at Item 18. of this annual report.

Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic inflammatory autoimmune disease causing inflammation, pain, and eventually joint damage and disability.

Kevzara®

Kevzara® (sarilumab) is a human monoclonal antibody that binds to the interleukin-6 receptor (IL-6R) and has been shown to inhibit IL-6R mediated signaling. IL-6 is a cytokine in the body that, in excess and over time, can contribute to the inflammation associated with rheumatoid arthritis. Kevzara® is available in 20 countries, including the US.

In May 2017, the FDA approved Kevzara® for the treatment of adult patients with moderately to severely active RA who have had an inadequate response or intolerance to one or more disease modifying anti-rheumatic drugs (DMARDs), such as methotrexate. In June 2017, the European Commission granted marketing authorization for Kevzara® in combination with methotrexate for the treatment

of moderately to severely active RA in adult patients who have responded inadequately to – or who are intolerant to – one or more DMARDs, such as methotrexate. The product is also in development in pediatric populations. See "— B.5. Global Research & Development".

Kevzara® is developed and commercialized in collaboration with Regeneron. For additional information, see "Item 5.Operating and Financial Review and Prospects — Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

Rare diseases

Our Rare Diseases business is focused on products for the treatment of rare genetic diseases and other rare chronic debilitating diseases of high unmet medical need, including lysosomal storage disorders (LSDs), a group of metabolic disorders caused by enzyme deficiencies.

Cerezyme®

Cerezyme® (imiglucerase) is an enzyme replacement therapy used to treat Gaucher disease, a chronic, inherited, progressive and potentially life-threatening LSD. Gaucher disease is caused by deficiency of the enzyme glucocerebrosidase; this causes a fatty substance called glucosylceramide (also called GL-1) to build up in certain areas of the body including the spleen, liver, and bone. Gaucher disease exhibits diverse manifestations, a broad range of age of onset of symptoms, and a wide clinical spectrum of disease severity. It is estimated that Gaucher disease occurs in approximately one in 120,000 newborns in the general population and one in 850 in the Ashkenazi Jewish population worldwide, but incidence and patient severity vary among regions. Cerezyme® has been marketed in the US since 1994, in the EU since 1997, in Japan since 1998 and in China since 2008, and is approved to treat Type 1 Gaucher disease in more than 85 countries. It has also been approved to treat the systemic symptoms of Type 3 Gaucher disease in most non-US markets, including the EU and Japan.

Cerezyme® is typically given by intravenous infusions for 1-2 hours every two weeks at an infusion center, a doctor's office, or at home as medically appropriate. The dose of Cerezyme® is individualized based on the weight of the patient and disease severity. The most common dosing schedule for Cerezyme® is 60 units per kilogram of body weight, every two weeks.

Cerdelga®

Cerdelga® (eliglustat) is the first and only first-line oral therapy for Gaucher disease Type 1 adult patients. A potent, highly specific ceramide analog inhibitor of GL-1 synthesis with broad tissue distribution, Cerdelga® has demonstrated efficacy in the treatment of naive Gaucher disease patients and in patients who switch from enzyme replacement therapy. Cerdelga® has been approved to treat Type 1 Gaucher disease in the US (2014), and in the EU and Japan (2015). It is also in development for the treatment of type I Gaucher disease in pediatric patients. See "— B.5. Global Research & Development".

Regarding patent infringement proceedings in US, see "Item 8. Information on Legal or Arbitration Proceedings - Cerdelga® Patent Litigation".

Myozyme® and Lumizyme®

Myozyme® (alglucosidase alfa) is an enzyme replacement therapy used to treat both Infantile Onset and Late Onset Pompe disease (IOPD and LOPD). Pompe disease is an inherited, progressive and often fatal neuromuscular disease, caused by a genetic deficiency or dysfunction of the lysosomal enzyme acid alpha-glucosidase (GAA) that results in the build-up of glycogen in the muscles' cells. For infantile-onset Pompe disease, symptoms begin within a few months of birth and there is impact to the heart in addition to skeletal muscle weakness. Other symptoms include difficulties breathing, frequent chest infections, problems feeding that result in failure to gain weight as expected, and failure to meet certain developmental milestones. Patients with late-onset Pompe disease typically present symptoms any time after the first year of life to late adulthood and rarely manifest cardiac problems. The hallmark symptom of late-onset Pompe disease is skeletal muscle weakness, which often leads to walking disability and reduced respiratory function. Patients often require wheelchairs to assist with mobility and may require mechanical ventilation to help with breathing. Pompe disease occurs in approximately one in 40,000 newborns worldwide, but incidence and patient severity vary among regions.

Myozyme® was first approved in 2006 in the EU and has since been approved in more than 70 countries. In the US, alglucosidase alfa has been marketed as Lumizyme® since 2010.

The recommended dosage regimen of Myozyme® and Lumizyme® is 20 mg per kilogram of body weight administered every two weeks as an intravenous infusion. Myozyme® should be reconstituted, diluted and administered by a healthcare professional.

Nexviazyme®

Nexviazyme® (avalglucosidase alfa-ngpt) is an important new treatment option for Pompe patients. Nexviazyme® is approved in the US to treat late-onset Pompe disease (LOPD) in patients age one year or above, in Canada for the treatment of LOPD patients older than 6 months and in Switzerland (Nexviadyme®) for all patients with LOPD.

In Japan and Australia, Nexviazyme® is approved for the treatment of both LOPD and IOPD Pompe patients. Nexviazyme® has also been approved by the regulatory authorities in Taiwan for use in IOPD and LOPD for patients aged 6 months and older. In 2022, it is anticipated that Nexviazyme® will launch in an additional 12 markets.

In Europe, Sanofi has requested a re-examination of a negative COMP (Committee for Orphan Medicinal Products) decision regarding the orphan drug designation of avalglucosidase alfa to delay the regulatory decision for several months.

Nexviazyme® is administered as a monotherapy enzyme replacement therapy every two weeks. The recommended dose is based on body weight (20 mg/kg for LOPD patients ≥30 kg or 40 mg/kg for LOPD patients <30 kg) and is administered incrementally via intravenous infusion. For IOPD patients in Australia the approval allows for dose escalation up to 40 mg/kg if the response observed at 20 mg/kg is considered insufficient. Nexviazyme® is also being investigated for the treatment of patients aged less than 6 months who are affected by infantile onset Pompe disease.

Fabrazyme®

Fabrazyme® (agalsidase beta) is an enzyme replacement therapy used to treat Fabry disease. Fabry disease (FD) is a multisystemic, progressive, X-linked inherited disorder of glycosphingolipid metabolism due to deficient or absent lysosomal α-galactosidase A activity resulting in progressive globotriaosylceramide (GL-3) accumulation in the lysosomes of various tissues. Fabry disease affects both genders. With age, progressive organ damage develops, leading to potentially life-threatening renal, cardiac and/or cerebrovascular complications. Fabry disease is characterized by different symptom severities and rates of progression, ranging from classic disease with early symptom onset to late onset disease with cardiac and/or renal complications later in life. Fabry disease occurs in approximately one in 35,000 newborns worldwide, but incidence and patient severity vary among regions. Fabrazyme® has been marketed in the EU since 2001 and in the US since 2003, and is approved in more than 70 countries.

The recommended dosage of Fabrazyme® is 1 mg per kilogram of body weight, infused intravenously every two weeks at an infusion center, a doctor's office, or at home as medically appropriate.

Aldurazyme®

Aldurazyme® (laronidase) is the only approved enzyme replacement therapy for mucopolysaccharidosis type 1 (MPS I), an inherited lysosomal storage disorder caused by a deficiency of alpha-L-iduronidase, a lysosomal enzyme normally required for the breakdown of certain complex carbohydrates known as glycosaminoglycans (GAGs). MPS I is multi-systemic, and children with MPS I are described as having either a severe or attenuated form of the disorder based on age of onset, severity of symptoms, rate of disease progression and whether there is early and direct involvement of the brain. MPS I occurs in approximately one per 100,000 live births worldwide, but incidence and patient severity vary among regions. Aldurazyme® has been marketed in the EU and the US since 2003, and is approved in more than 75 countries.

The recommended dosage regimen of Aldurazyme® is 0.58 mg per kilogram of body weight, administered once weekly as an intravenous infusion.

Oncology

Sarclisa®

Sarclisa® (isatuximab) is a monoclonal antibody that binds a specific epitope on the human CD38 receptor and has antitumor activity via multiple mechanisms of action. It was approved in March 2020 in the US in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor, and by the European Commission in May 2020 in combination with pomalidomide and dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy. Sarclisa® is now approved in more than 25 countries.

Sarclisa® was approved for a label extension in combination with carfilzomib and dexamethasone in March 2021 in the US for the treatment of adults with relapsed or refractory multiple myeloma (RRMM) who have received one to three prior lines of therapy, and by the European Commission in April 2021 for the treatment of adult patients with multiple myeloma (MM) who have received at least one prior therapy. The Japanese Ministry of Health, Labor and Welfare (MHLW) granted approval for Sarclisa® in combination with carfilzomib and dexamethasone, in combination with dexamethasone, and as monotherapy for RRMM patients in November 2021. Sarclisa® is also under investigation in several clinical studies for the treatment of hematologic malignancies and other hematologic indications.

Libtayo®

Libtayo® (cemiplimab-rwlc), an immune therapy drug, is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1). This may restore immune function through the activation of cytotoxic T cells, thereby avoiding tumor evasion from host immunity.

In September 2018, the FDA approved Libtayo® for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. The European Commission granted conditional marketing authorization in July 2019. Libtayo® is the only treatment specifically approved and available for advanced CSCC in the EU. CSCC is the second most common form of skin cancer.

Libtayo® received approval in the US for the treatment of adult patients with metastatic basal cell carcinoma (mBCC) and for the treatment of adult patients with locally advanced basal cell carcinoma (laBCC) in February 2021. The European Commission granted marketing authorization for Libtayo® for the treatment of adult patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have progressed on or are intolerant to a hedgehog pathway inhibitor (HHI) in June 2021. Libtayo® received approval in the US in February 2021 for the treatment of adult patients with non-small lung cancer (NSCLC) whose tumors have high PD-L1 expression (Tumor Proportion Score of at least 50%) and are not candidates for surgical resection or definitive chemoradiation or have metastatic disease. In June 2021, the European Commission granted marketing authorization for the first-line treatment of adult patients with NSCLC expressing PD-L1 (in 50% tumor cells), with no EGFR, ALK or ROS1 aberrations, who have locally advanced NSCLC and who are not candidates for definitive chemoradiation, or who have metastatic NSCLC. Libtayo® is currently approved in 25 countries.

Libtayo® was filed for label extensions with the FDA and the EMA in 2L+ cervical cancer in 2021. On January 27, 2022, Sanofi and Regeneron announced the voluntary withdrawal of the supplemental Biologics License Application. Discussions with regulatory authorities outside of the US are ongoing. Libtayo® is currently under review by the FDA in chemotherapy combination as a first-line treatment for NSCLC. See "— B.5. Global Research & Development".

Libtayo® is developed and commercialized in collaboration with Regeneron Pharmaceuticals, Inc. For additional information on the collaboration, see "Item 5.Operating and Financial Review and Prospects — Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

Jevtana®

Jevtana® (cabazitaxel), a chemotherapy drug and cytotoxic agent, is a semi-synthetic second-generation taxane that prevents many cancer cells from dividing, which ultimately results in destroying many such cells. It is approved in combination with prednisone for the treatment of patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing treatment regimen. Jevtana® was granted marketing authorization by the FDA in June 2010, by the European Commission in March 2011, and in Japan in July 2014. The product is marketed in over 75 countries. In Europe, generic competition started for Jevtana® from the end of March 2021. In the US, the Jevtana® composition of matter patent expired in September 2021. Sanofi has filed patent infringement suits under the US Hatch-Waxman Act against generic manufacturers for cabazitaxel in the US District Court for the District of Delaware asserting three Orange Book listed US patents for Jevtana®. Sanofi has entered settlement agreements with some of the defendants and the suit against the remaining defendants is ongoing; see Note D.22.b. to the consolidated financial statements, included at Item 18. of this annual report.

Fasturtec®/Elitek®

Fasturtec®/Elitek® is used for the management of plasma uric levels in patients with leukemia, lymphoma, and solid tumor malignancies receiving anticancer therapies.

Rare blood disorders

The Rare Blood Disorders franchise was created in 2018 following Sanofi's acquisition of Bioverativ and Ablynx (see "— A. History and Development of the Company").

Eloctate®

Eloctate® (antihemophilic factor (recombinant), Fc fusion protein) is an extended half-life clotting-factor therapy to control and prevent bleeding episodes in adults and children with hemophilia A. In the US, it is indicated for use in adults and children with hemophilia A for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.

Hemophilia A is a rare, x-linked genetic bleeding disorder characterized by a deficiency of functional coagulation Factor VIII, resulting in a prolonged patient plasma-clotting time. As a consequence, people with hemophilia A bleed for a longer time than normal. Eloctate® temporarily replaces the missing coagulation Factor VIII by intravenous injection.

We market Eloctate® primarily in the US (since 2014), Japan, Canada, Australia, South Korea and Taiwan.

Eloctate® is developed and commercialized in collaboration with Swedish Orphan Biovitrum AB (Sobi), whose territories include Europe, Russia, the Middle East, and some countries in North Africa.

Alprolix®

Alprolix® (coagulation Factor IX (recombinant), Fc fusion protein) is an extended half-life clotting-factor therapy to control and prevent bleeding episodes in adults and children with hemophilia B. In the US, it is indicated for use in adults and children with hemophilia B for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.

Hemophilia B is a rare, x-linked genetic bleeding disorder characterized by a deficiency of functional coagulation Factor IX, resulting in a prolonged patient plasma-clotting time. As a consequence, people with hemophilia B bleed for a longer time than normal. Alprolix® temporarily replaces the missing coagulation Factor IX by intravenous injection.

We market Alprolix® primarily in the US (since 2014), Japan, Canada, Australia, New Zealand, South Korea and Taiwan.

Alprolix® is developed and commercialized in collaboration with Swedish Orphan Biovitrum AB (Sobi), whose territories include Europe, Russia, the Middle East, and some countries in North Africa.

Cablivi®

Cablivi® (caplacizumab) is a bivalent anti-von Willebrand Factor (vWF) Nanobody® for the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP). Cablivi® is the first therapeutic specifically indicated for the treatment of aTTP.

Acquired thrombotic thrombocytopenic purpura is an ultra-rare (3.5-4.5 episodes per million of population), life-threatening, autoimmune-based blood clotting disorder characterized by extensive clot formation in small blood vessels throughout the body, leading to severe thrombocytopenia (very low platelet count); microangiopathic hemolytic anemia (loss of red blood cells through destruction); ischemia (restricted blood supply to parts of the body); and widespread organ damage, especially in the brain and heart. Cablivi® has an immediate effect on platelet adhesion and the ensuing formation and accumulation of the micro-clots.

Cablivi® was granted marketing authorization by the European Commission in September 2018 and by the FDA in February 2019. Cablivi® is available in more than 20 countries including the US, the majority of European countries (14), Brazil, and Greater Gulf region states. Additional commercial launches are ongoing.

Cablivi® was developed by Ablynx, a Sanofi company since mid-2018. See "- A. History and Development of the Company".

General Medicines

Sanofi has prioritized core assets with differentiated and/or established profiles that have significant opportunity for growth in key markets. Some of these well-established medicines are the standard-of-care for patients living with diabetes or cardiovascular disease. These core assets include Toujeo®, Soliqua®, Praluent®, Multaq®, Lovenox®, and Plavix®.

Diabetes

Lantus®

Lantus® (insulin glargine 100 units/mL) is a long-acting analog of human insulin, indicated for once-daily administration for the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. Lantus® relies on more than 15 years of clinical evidence in diabetes treatment and a well established safety profile. Approved in the US and the EU in 2000 and in Japan in 2008, Lantus® is available in over 130 countries worldwide. Two insulin glargine biosimilars are available in the US, two in European markets, and two in Japan.

There are ongoing patent infringement proceedings in the US against Mylan. See “Item 8. Financial information — Information on Legal or Arbitration Proceedings”.

Toujeo®

Toujeo® (insulin glargine 300 units/mL) is a long-acting analog of human insulin, indicated for the treatment of diabetes mellitus in adults. Toujeo® has been granted marketing authorization by the FDA (February 2015); the European Commission (April 2015); and the Ministry of Health, Labor and Welfare (J-MHLW) in Japan, where its approved brand name is Lantus® XR (June 2015). Toujeo® has now been launched in more than 60 countries, including China since the end of 2020. In January 2020, the European Commission approved an expansion of the indication to include the treatment of diabetes in adolescents and children (aged 6 years and above).

Toujeo® is available in Toujeo® SoloSTAR®, a disposable prefilled pen which contains 450 units of insulin glargine and requires one-third of the injection volume to deliver the same number of insulin units as Lantus® SoloSTAR®. In the US (since 2018) and the EU (since 2019), Toujeo® is also available in a disposable prefilled pen which contains 900 units of insulin glargine. In India, Toujeo is also available in a dedicated 450-unit cartridge in combination with a dedicated reusable pen (TouStar®).

Apidra®

Apidra® (insulin glulisine) is a rapid-acting analog of human insulin, indicated to improve glycemic control in adults and children with diabetes mellitus. It is administered around meal time, and is used in a regimen with an intermediate or long-acting insulin (Apidra® has a more rapid onset and shorter duration of action than fast-acting human insulin). Apidra® is available in over 100 countries worldwide.

Soliqua® – Suliqua®

Soliqua® 100/33 or Suliqua® is a once-daily fixed-ratio combination of insulin glargine 100 Units/mL, a long-acting analog of human insulin, and lixisenatide, a GLP-1 receptor agonist. The FDA approved Soliqua® 100/33 in November 2016 for the treatment of adults with type 2 diabetes inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide; and in February 2019 for patients uncontrolled on oral antidiabetic medicines. In January 2017, Suliqua® (the product’s brand name in Europe) was approved for use in combination with metformin for the treatment of adults with type 2 diabetes to improve glycemic control, when this has not been provided either by metformin alone or by metformin combined with another oral glucose-lowering medicinal product or with basal insulin. In Japan, Soliqua® was approved in May 2020 for type 2 diabetes mellitus, where treatment with insulin is required. Suliqua® is available in over 40 countries.

Admelog®/Insulin lispro Sanofi®

Admelog® (or Insulin lispro Sanofi®) is a rapid-acting insulin similar to Humalog®, another insulin lispro 100 Units/mL. Admelog® was approved by the FDA in December 2017, and was also granted marketing authorization as a biosimilar (under the proprietary name Insulin lispro Sanofi®) by the European Commission in July 2017. It is used to improve blood sugar control in adults with type 2 diabetes and adults and children (aged 3 years and above) with type 1 diabetes. Admelog® was launched in the US and several European countries during 2018.

Amaryl®/Amarel®/Solosa®

Amaryl® (glimepiride) is an orally administered once-daily sulfonylurea available in single form or in combination with metformin, indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. A number of glimepiride generics are available in most markets.

Truvelog™/Insulin aspart Sanofi®

Truvelog™ (also known as TruRapi™ or Insulin aspart Sanofi®) is a rapid-acting insulin similar to Novorapid®/Novolog®, another insulin aspart 100 Units/mL. It was granted marketing authorization as a biosimilar (under the proprietary name Insulin aspart Sanofi®) by the European Commission in June 2020. It is used to improve blood sugar control in adults with type 2 diabetes, and in adults and children (aged 1 year and above) with type 1 diabetes. Insulin aspart Sanofi® was launched in several European countries during 2020.

Integrated Digital Care Solutions

Sanofi, in collaboration with Abbott and Biocorp, Health2Sync and Roche, is building a connected set of digital tools and features to support people living with diabetes and taking insulin. Sanofi intends to use aggregated de-identified data to generate insights to inform patients and providers, and to evaluate additional clinical or quality-of-life outcomes. Successful launches in several countries demonstrate the value of the integration of digital tools into a fully connected ecosystem.

Cardiovascular diseases and established prescription products

Praluent®

Praluent® (alirocumab) is a human monoclonal antibody (mAb) for self-administered injection every two weeks or once-monthly. It blocks the interaction of proprotein convertase subtilisin/kexin type 9 (PCSK9) with low-density lipoprotein (LDL) receptors, increasing the recycling of LDL receptors and reducing LDL cholesterol levels.

Praluent® is indicated as an adjunct to diet and maximally tolerated statin therapy in certain adult patients with uncontrolled LDL cholesterol. Praluent® has been approved in more than 60 countries worldwide, including the US (in 2015), Canada and Switzerland, as

well as in the European Union (in 2015). In 2018, the FDA approved a Praluent® label update for some patients currently requiring LDL apheresis therapy. In March 2019 in the EU and in April 2019 in the US, Praluent® was approved for use in patients with established cardiovascular disease to reduce the risk of cardiovascular events.

In December 2019, Praluent® was approved in China, where it started to be commercialized in May 2020.

Since April 2020, Praluent® has no longer been commercialized in collaboration with Regeneron. Regeneron is responsible for commercialization in the US, and Sanofi for all other markets outside the US. For additional information on the commercialization of this product, see "Item 5. Operating and Financial Review and Prospects — Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

In October 2020, the European Patent Office Technical Boards of Appeal ruled in Sanofi/Regeneron's favor, invalidating claims of Amgen's European Patent No. 2215124 relevant to Praluent® for lack of inventive step. This means that Praluent® will continue to be marketed and sold in the EU.

Multaq®

Multaq® (dronedarone) is an oral multichannel blocker with anti-arrhythmic properties for prevention of atrial fibrillation recurrences in certain patients with a history of paroxysmal or persistent atrial fibrillation. Multaq® was approved in the US and in the EU in 2009. Multaq® is available in about 35 countries.

Plavix®/Iscover®

Plavix® or Iscover® (clopidogrel bisulfate) is a platelet adenosine diphosphate (ADP) receptor antagonist. It is indicated for the prevention of atherothrombotic events in patients with a history of recent myocardial infarction (MI), recent ischemic stroke or established peripheral arterial disease (PAD), and for patients with acute coronary syndrome (ACS). Plavix® is also indicated in combination with acetylsalicylic acid (ASA) for the prevention of atherothrombotic and thromboembolic events in atrial fibrillation, including stroke.

CoPlavix®/DuoPlavin®, a fixed-dose combination of clopidogrel bisulfate and ASA, is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndrome who are already taking both clopidogrel and ASA.

A number of clopidogrel bisulfate generics have been launched in most markets. Plavix® or Iscover® are available in more than 80 countries. For additional information on the commercialization of these products, see "Item 5. Operating and Financial Review and Prospects — Financial Presentation of Alliances — Alliance Arrangements with Bristol-Myers Squibb".

Sanofi is involved in two Plavix® product lawsuits. See Note D.22.c) to our consolidated financial statements, included at Item 18. of this annual report.

Lovenox®/Clexane®

Lovenox® or Clexane® (enoxaparin sodium) is a low molecular weight heparin (LMWH) indicated for use in the prophylaxis and treatment of venous thromboembolism and in the treatment of acute coronary syndrome. Enoxaparin generics are available in the US, and biosimilar enoxaparin products have gradually become available across various European countries and in a growing number of international markets. Lovenox® or Clexane® is marketed in more than 100 countries.

Aprovel®/Avapro®/Karvea®

Aprovel®, also known as Avapro® or Karvea® (irbesartan), is an angiotensin II receptor antagonist indicated as a first-line treatment for hypertension and for the treatment of nephropathy in hypertensive patients with type 2 diabetes. We also market CoAprovel®/Avalide®/Karvezide®, a combination of irbesartan and the diuretic hydrochlorothiazide. A combination with amlodipine (Aprovasc®) has been launched in several emerging market countries.

A number of irbesartan generics have been launched in most markets. Aprovel® and CoAprovel® are marketed in more than 80 countries. For additional information on the commercialization of this product, see "Item 5. Financial Presentation of Alliances — Alliance Arrangements with Bristol-Myers Squibb". In Japan, the product is licensed to Shionogi Co. Ltd and BMS KK. BMS KK has sublicensed the agreement to Dainippon Pharma Co. Ltd.

Renagel® and Renvela®

Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate) are oral phosphate binders used by chronic kidney disease (CKD) patients on dialysis as well as late stage CKD patients in Europe to treat hyperphosphatemia, or elevated phosphorus levels, which is associated with heart and bone disease. Renvela® is a second-generation buffered phosphate binder.

Generics of sevelamer carbonate are available in the US and in various European countries. A generic of sevelamer hydrochloride was approved in the US in February 2019, and was subsequently launched. Renagel® and Renvela® are marketed in more than 85 countries. In Japan and several Pacific Rim countries, Renagel® is marketed by Chugai Pharmaceutical Co., Ltd and its sublicensee, Kyowa Hakko Kirin Co., Ltd.

Synvisc®/Synvisc-One®

Synvisc® and Synvisc-One® (hylan G-F 20) are viscosupplements used to treat pain associated with osteoarthritis. Synvisc® and Synvisc-One® are marketed in over 60 countries.

Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 50 years and remains a reference treatment for epilepsy worldwide. Depakine® is also a mood stabilizer, registered in the treatment of manic episodes associated with bipolar disorder (in some countries this indication is branded differently, for example as Depakote® in France). We hold no rights to Depakine® in the US, and sodium valproate generics are available in most markets.

Sanofi is involved in product litigation related to Depakine®. See Note D.22.a) to the consolidated financial statements included at Item 18. of this annual report.

Legacy oncology and transplant

Thymoglobulin®

Thymoglobulin® (anti-thymocyte Globulin) is a polyclonal anti-human thymocyte antibody preparation that acts as a broad immunosuppressive and immunomodulating agent. In the US, Thymoglobulin® is indicated for the prophylaxis and treatment of acute rejection in patients receiving a kidney transplant, used in conjunction with concomitant immunosuppression. Outside the US, depending on the country, Thymoglobulin® is indicated for the treatment and/or prevention of acute rejection in organ transplantation; immunosuppressive therapy in aplastic anemia; and the treatment and/or prevention of Graft-versus-Host Disease (GvHD) after allogeneic hematopoietic stem cell transplantation. Thymoglobulin® is currently marketed in over 65 countries.

Taxotere®

Taxotere® (docetaxel), a chemotherapy drug and cytotoxic agent, is a semi-synthetic taxane. It has been approved for use in 11 indications in five different tumor types (breast, prostate, gastric, lung, and head and neck). Generics of docetaxel have been launched globally.

Sanofi is involved in Taxotere® product litigation in the US. See Note D.22.a) to our consolidated financial statements, included at Item 18. of this annual report.

Eloxatin®

Eloxatin® (oxaliplatin), a chemotherapy drug, is a platinum-based cytotoxic agent. In combination with the infusional administration of two other chemotherapy drugs (5-fluorouracil/leucovorin, in the FOLFOX regimen), Eloxatin® is approved by the FDA for adjuvant treatment of people with stage III colon cancer who have had their primary tumors surgically removed. It is also approved for the treatment of advanced colorectal cancer and in some countries for the treatment of early-stage gastric cancer. Generics of oxaliplatin have been launched globally. Eloxatin® is in-licensed from Debiopharm.

Mozobil®

Mozobil® (plerixafor injection) is a hematopoietic stem cell mobilizer. It is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM). Mozobil® is marketed in over 65 countries.

Rezurock™

Rezurock™ (belumosudil) is a selective ROCK2 (rho-associated coiled-coil–containing protein kinase-2) inhibitor. It was approved in July 2021 by the FDA for the treatment of adult and pediatric patients aged 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy. Activities are ongoing to ensure registration in other territories.

Zaltrap®

Zaltrap® (aflibercept/ziv-aflibercept) is a recombinant fusion protein. The FDA approved Zaltrap® in August 2012 for use in combination with FOLFIRI (a chemotherapy regimen made up of 5-fluorouracil/leucovorin/irinotecan), in patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. To avoid confusion with Eylea®, the FDA assigned a new name, ziv-aflibercept, to the active ingredient. The European Commission approved Zaltrap® (aflibercept) in February 2013 to treat mCRC that is resistant to or has progressed after an oxaliplatin-containing regimen.

Zaltrap® is marketed in 50 countries. For additional information on the commercialization of Zaltrap®, see "Item 5. Operating and Financial Review and Prospects — Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

Generics

On September 30, 2018, we completed the divestment of our European generics business Zentiva to Advent International, a US global private equity firm. We have retained our presence in Generics in Emerging Markets, especially in Latin America with two top-of-mind brands – Medley (Brazil) and Genfar (Colombia, Peru, Ecuador and Central America) – and also in Russia, South Africa and Turkey.

B.3. Vaccine products

Sanofi Pasteur, the Vaccines division of Sanofi, is a world leader in the vaccine industry and a key supplier of life-saving vaccines all over the world and for publicly funded international stakeholders such as UNICEF, the Pan American Health Organization (PAHO) and the Global Alliance for Vaccines and Immunization (GAVI).

The Sanofi Pasteur portfolio includes the following vaccines:

a) Poliomyelitis, pertussis and hib pediatric vaccines

Sanofi Pasteur is one of the key players in pediatric vaccines in both developed and emerging markets, with a broad portfolio of standalone and combination vaccines protecting against up to six diseases in a single injection. Due to the diversity of immunization schedules throughout the world, vaccines vary in composition according to regional specificities.

Tetraxim®, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis and poliomyelitis (polio), was first marketed in 1998. To date, the vaccine has been launched in close to 90 countries outside the US.

Pentaxim®, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis, polio and Hemophilus influenzae type b (Hib), was first marketed in 1997. To date, the vaccine has been launched in more than 100 countries outside the US. In most European, Latin American, Asian and Middle Eastern markets, Pentaxim® is being gradually replaced by Hexaxim®.

Hexaxim®/Hexyon®/Hexacima® is a fully liquid, ready-to-use 6-in-1 (hexavalent) pediatric combination vaccine that provides protection against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. Hexaxim® is the only combination vaccine including acellular pertussis (acP) and inactivated polio vaccines (IPV) currently prequalified by the WHO. Hexaxim® is now available in more than 100 countries outside the US.

Pentacel®, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis, polio and Hib, was launched in the US in 2008.

Quadracel ® is a vaccine indicated for active immunization against diphtheria, tetanus, pertussis and poliomyelitis, used in children aged 4 through 6 years as a fifth dose in the diphtheria, tetanus, pertussis vaccination (DTaP) series, and as a fourth or fifth dose in the inactivated poliovirus vaccination (IPV) series.

Shan5® is a 5-in-1 (whole-cell pertussis based) combination vaccine protecting against five diseases (diphtheria, tetanus, pertussis, Hib and hepatitis B). Shan5® is WHO pre-qualified and procured through Unicef to the GAVI countries.

Act-Hib® is a standalone vaccine protecting against Hib, and is mainly distributed in the US, Japan and China in conjunction with pertussis combination vaccines that do not contain the Hib valence.

Sanofi Pasteur is a leading provider of polio vaccines and has been a partner of the Global Polio Eradication Initiative (GPEI) for over 30 years, with more than 13 billion doses of oral polio vaccines (OPV) delivered during that time.

Since 2014, when the WHO recommended that every child should receive at least one dose of IPV, Sanofi Pasteur has provided 395 million doses to support the WHO “Polio End Game” strategy for the world's 73 poorest countries, representing 80% of the total IPV volumes used in those countries.

Vaxelis® is a hexavalent combination vaccine protecting against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. This vaccine (developed and distributed in partnership with Merck) was approved in 2016 by the EMA and is distributed in various EU countries. Vaxelis® was approved by the FDA in December 2018, becoming the first hexavalent vaccine to be approved in the US, and launched in the US in June 2021.

b) Influenza vaccines

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines, offering several distinct influenza vaccines that are sold globally to meet growing demand.

Fluzone® Quadrivalent is a quadrivalent inactivated influenza vaccine, produced in the US, containing two type A antigens and two type B antigens in order to provide increased protection against more circulating strains of influenza viruses. Fluzone® Quadrivalent/FluQuadri® is available in 13 countries (including the US) for children aged over six months, adolescents and adults. Fluzone® 0.5ml QIV is the currently-licensed standard dose (15 µg/strain) quadrivalent influenza vaccine for ages 6 months and older.

Fluzone® High-Dose Quadrivalent, designed specifically to provide greater protection against influenza for people aged 65 years and older, was approved by the FDA in November 2019. It has now fully replaced Fluzone® High-Dose Trivalent, and contains two influenza A and two influenza B strains at 60µg/strain. Fluzone® High-Dose Quadrivalent was approved in the EU in the second quarter of 2020, under the name Efluelda®, indicated for adults aged 60 years or older. Both Fluzone® High-Dose Quadrivalent and Efluelda® have been available since the 2020/21 influenza season.

Flublok® is a quadrivalent influenza vaccine for adults aged 18 and older. It is the only recombinant protein-based influenza vaccine approved by the FDA. Flublok® is currently sold in the US, the United Kingdom, Hong Kong and Taiwan, with continued global expansion planned over the next several years. Flublok® was approved in the EU under the name Supemtek® in November 2020.

Vaxigrip® is a trivalent influenza vaccine, containing two antigens against type A influenza viruses and one antigen against type B influenza viruses. It has now been replaced by VaxigripTetra® in most countries.

VaxigripTetra® is the quadrivalent (QIV) version of Vaxigrip®, including two antigens against A strains of influenza viruses and two antigens against B strains. Compared to the trivalent influenza vaccine, it contains an additional influenza B strain; it was licensed in 2016 and has been launched in more than 90 countries since 2017. VaxigripTetra® is not licensed in the US where Fluzone® Quadrivalent, which is produced in the US, is distributed.

c) Booster vaccines

Adacel® is the first trivalent booster vaccine offering protection against diphtheria, tetanus and pertussis. The vaccine can be used from 4 years of age following primary immunization and is the first Tdap vaccine indicated for use during pregnancy for protection against pertussis in newborns. It is available in 55 countries including the US, and otherwise mostly in Europe, Asia and Latin America.

Repevax®/Adacel®-Polio is a combination vaccine that provides protection against diphtheria, tetanus, pertussis and polio. It is the first Tdap-IPV vaccine indicated for use during pregnancy for protection against pertussis in newborns. It is currently marketed in 26 countries outside the US, with a strong focus on European markets (such as France and Germany).

d) Meningitis vaccines

Menactra® is the first quadrivalent conjugate vaccine against meningococcal meningitis (serogroups: A, C, Y, and W-135), one of the deadliest forms of meningitis. Menactra® is indicated for people aged 9 months through 55 years in the US, Canada, several Middle Eastern countries including Saudi Arabia, and numerous other countries (outside Europe). It is a strong leader in the meningitis quadrivalent market in the US and globally. More than 100 million doses of Menactra® have been distributed since launch. It is the only fully liquid (no reconstitution needed) meningitis quadrivalent conjugated vaccine available in the market.

MenQuadfi® is a novel fully-liquid meningococcal quadrivalent conjugate vaccine formulation. It is expected to have a broad age indication from infants (6 weeks) to the elderly, with flexible dosing schedules. It is also expected to be available worldwide, allowing Sanofi Pasteur to enter the European meningococcal market where it was not previously present. MenQuadfi® is the first and only quadrivalent ACWY vaccine to demonstrate superior immune response against serogroup C in toddlers compared to a monovalent serogroup C vaccine

(standard-of-care in multiple markets in Europe and internationally). MenQuadfi® was approved in the US in April 2020 for people aged two years and older. It was approved in Australia, Canada, the EU and other European Economic Area countries in October and November 2020, and subsequently in Argentina, Brazil and Chile, for people aged 12 months and older. Marketing approval is pending in numerous other countries. Extension of the age indication in these markets down to six weeks will follow submission of additional Phase III data. MenQuadfi® was launched in the US in March 2021 and in Europe in August 2021.

e) Travel and endemic vaccines

Sanofi Pasteur provides a wide range of travel and endemic vaccines including hepatitis A, typhoid, cholera, yellow fever, Japanese encephalitis and dengue, as well as rabies vaccines and immunoglobulins. These products are used in endemic settings in the developing world and are the foundation for important partnerships with governments and organizations such as UNICEF. They are also used by travelers and military personnel in industrialized countries and in endemic areas.

B.4. Consumer Healthcare

In 2021, our Consumer Healthcare operations became a standalone business unit with integrated R&D and manufacturing functions plus dedicated support functions and information technology. Implementation progressed as planned in 2021, with more than half of the legal entities created. In addition, we announced the divestment and discontinuation of 111 non-core brands in Europe, the US and Latin America. This program aims to simplify the portfolio and reduce the number of brands from 250 to about 100 by 2022. We will also optimize the Go-To-Market model by tailoring it more closely to the actual needs of our markets.

Our CHC sales are supported by a range of products, including the following brands:

Allergy, cough & cold

- Allegra® comprises a range of fexofenadine HCl–based products. Fexofenadine is an anti-histamine for relief from allergy symptoms including sneezing, runny nose, itchy nose or throat, and itchy, watery eyes. The Allegra® brand family is sold in more than 80 countries across the world.
- Mucosolvan® is a cough brand with many different formulations. It contains the mucoactive agent ambroxol; this stimulates synthesis and release of surfactant. It is sold in various countries in Europe, Latin America and Asia, and in Russia.

Pain

- Doliprane® offers a range of paracetamol/acetaminophen-based products for pain and fever with a wide range of dosage options and pharmaceutical forms, and is sold mainly in France and various African countries.
- The Buscopan® range (hyoscine butylbromide) has an antispasmodic action that specifically targets the source of abdominal pain and discomfort. It is sold across the globe.
- We also have local pain brands such as Eve® in Japan; Dorflex® and Novalgina® in Brazil; and Icy Hot® and Aspercreme® in the US.

Digestive

- Dulcolax® products offer a range of constipation solutions from predictable overnight relief to comfortable natural-feeling relief. The products are sold in over 80 countries. Dulcolax® tablets contain the active ingredient bisacodyl or sodium picosulfate, which works directly on the colon to produce a bowel movement.
- Enterogermina® is a probiotic indicated for the maintenance and restoration of intestinal flora in the treatment of acute or chronic intestinal disorders. Enterogermina® is sold primarily in Europe, and in Latin America and parts of Asia.
- Essentiale® is a natural soybean remedy to improve liver health. It is composed of essential phospholipids extracted from highly purified soya and contains a high percentage of phosphatidylcholine, a major component of the cell membrane. Essentiale® is used in fatty liver disease and is sold mainly in Russia, Eastern Europe, various countries in Southeast Asia, and China.
- Zantac 360°™ products are for the prevention and relief of heartburn, with a new formula launched in 2021 in North America.

Nutritional

- Nutritionals include a range of products to maintain general health, provide immune system support, or supplement vitamin deficiencies. These products help manage energy, stress, sleep and anxiety, and include a number of brands across the globe including Nature's Own® in Australia to improve and maintain health; Pharmaton® (mainly in Europe and Latin America); Magne B6® in Europe; and a range of sleep brands, including Novanuit® in Europe, Unisom® in USA and Drewell® in Japan.

Other

- Gold Bond® offers a broad range of products including daily body lotions, anti-itch products, moisturizing and soothing lotions, body and foot creams and powders for eczema. Gold Bond® is only sold in the US.

Starting from 2021 we are taking a more granular approach and focus on attractive sub-categories in key geographies, based on consumer trends, portfolio strengths and opportunities. These sub-categories include Allergy, Pain, Liver Care, Physical and Mental Wellness, and Probiotics. These sub-categories in our key geographies account for about one-third of our total CHC business today.

B.5. Global research & development

Over recent years, Sanofi has reshaped its R&D strategy, strengthening the development of innovative products that aim to substantially elevate the standard of care for patients, and prioritizing therapeutic areas where patient need is most urgent: oncology, immunology, rare

blood disorders and neurology. The objective is to develop transformative medicines with the potential to change patients' lives. However, discovering and developing a new product is a costly, lengthy and uncertain process and our continuous investments in research and development for future products and for the launches of newly registered molecules could result in increased costs without a proportionate increase in revenues. See “Item 3.D. Risk Factors” for further information.

In development, sustained efforts are being made to accelerate the pace of delivery for patients, adopting streamlined governance and seeking to push decision-making downward with strong team empowerment.

Our aspiration is to build a pipeline of first-in-class or truly differentiated best-in-class medicines, with two-thirds of biologic compounds and two-thirds of the pipeline directly derived from Sanofi internal research.

As part of our strategic framework, seven potentially transformative therapies in areas of high unmet patient need were prioritized: Dupixent® (multiple indications in Immunology & Inflammation), fitusiran and efanesoctocog alfa (hemophilia); amcenestrant (breast cancer); amlitelimab (Immunology & Inflammation); nirsevimab (respiratory syncytial virus); and tolebrutinib (multiple sclerosis).

Efforts to strengthen our pipeline with innovative assets in oncology and immune diseases, which included the acquisition of Principia Biopharma and Synthox in 2020, continued in 2021 when we completed the acquisition of Kiadis (a clinical-stage biopharmaceutical company developing next generation, “off-the-shelf”, NK cell-therapies) and of Kymab Group Ltd. (adding to our portfolio a fully human monoclonal antibody targeting the key immune system regulator OX40L). In our efforts to accelerate the development of transformative vaccines and therapies using mRNA technology, we acquired Translate Bio and Tidal Therapeutics, adding mRNA-based research platforms with applications in vaccines, oncology, immunology, and other disease areas. Sanofi also acquired Kadmon Holdings, Inc. to further strengthen growth and expansion for our General Medicines portfolio. In December 2021, we announced that we had entered into an agreement to acquire immuno-oncology company Amunix Pharmaceuticals, with the intention of accelerating and expanding our contributions to innovative medicines for oncology patients.

B.5.1. Pharmaceuticals

B.5.1.1. Products in development

For 2021, the main pipeline events related to the pharmaceuticals portfolio were:

Project	Potential Indication	Change	Reason
amlitelimab (SAR445229) – Anti-OX40L mAb (KY1005)	Atopic dermatitis	Added	Acquired from Kymab
alomfilimab (SAR445256) – Anti-ICOS mAb (KY1004)	Triple negative breast cancer	Added	Acquired from Kymab
SAR445419 – NK cell-based immunotherapy (KDS1001)	Acute myeloid leukemia	Added	Acquired from Kiadis
SAR445710 – Anti PD-L1/IL-15 fusion protein (KD033)	Solid tumors	Added	Acquired from Kadmon
SAR441566 – TNFa inhibitor	Inflammatory indications	Added	Entered confirmatory development
SAR444656 – IRAK4 degrader	Atopic dermatitis	Added	Entered confirmatory development
SAR443216 - Anti-CD3/CD28/HER2 trispecific mAb	Gastric cancer	Added	Entered confirmatory development
SAR443809 – Anti-Factor Bb antibody	Rare renal diseases	Added	Entered confirmatory development
SAR442970 – Anti-TNFa/OX40L NANOBODY®	Inflammatory indications	Added	Entered confirmatory development
SAR443726 – Anti-IL13/OX40L NANOBODY®	Atopic dermatitis	Added	Entered confirmatory development
SAR444336 – Pegylated-IL2	Inflammatory indications	Added	Entered confirmatory development
SAR443765 – Anti-IL13/TSLP NANOBODY®	Inflammatory indications	Added	Entered confirmatory development
SAR442999 – Anti-TNFa/IL23A NANOBODY®	Inflammatory indications	Added	Entered confirmatory development
SAR443579 - Anti-NKp46/CD123 mAb	Acute myeloid leukemia	Added	Entered confirmatory development
Nexviazyme® (GZ402666)	Pompe disease		Commercialized
ST400 – Ex Vivo ZFN Gene-Edited Cell Therapy	Beta-thalassemia	Removed	Development discontinued
SAR445136 – Ex Vivo ZFN Gene-Edited Cell Therapy	Sickle cell disease	Removed	Development discontinued
rilzabrutinib (SAR444671) – BTK inhibitor	Pemphigus Vulgaris	Removed	Development discontinued*
venglustat (GZ402671) - Oral GCS inhibitor	Autosomal dominant polycystic kidney disease	Removed	Development discontinued**
SAR440234 – Bispecific (CD123/CD3) T cell engager	Leukemia	Removed	Development discontinued
SAR441236 – Trispecific Neutralizing mAb	HIV	Removed	Development discontinued
REGN4018 – Anti-MUC16xCD3 bispecific mAb	Ovarian cancer	Removed	Development discontinued***
REGN5458 – Anti-BCMAxCD3 bispecific mAb	Relapsed refractory multiple myeloma	Removed	Development discontinued***
REGN5459 – Anti-BCMAxCD3 bispecific mAb	Relapsed refractory multiple myeloma	Removed	Development discontinued***
SAR439459 – TGFb inhibitor	Advanced solid tumors	Removed	Development discontinued
SAR442085 – Anti-CD38 mAb Fc engineered	Multiple myeloma	Removed	Development discontinued

mAb: monoclonal antibody

* *The development of rilzabrutinib was discontinued in this indication in September 2021.*

** *The development of venglustat was discontinued in this indication in June 2021*

*** *Opt-in rights were not exercised for these products from Regeneron.*

The clinical portfolio of new products as of December 31, 2021 is summarized in the table below; where several indications are being developed for one product, each indication is regarded as a separate project and specified individually.

For more information on Dupixent®, Kevzara®, Aubagio®, Cerdelga®, Libtayo®, Sarclisa® and Nexviazyme® see also "— Item 4. Information on the Company — B. Business Overview — B.2. Main Pharmaceutical Products".

	Phase I	Phase II	Phase III/registration
Oncology	**SAR442720** + pembrolizumab (non-small cell lung cancer 1st line) **SAR444245** mono & combo (solid tumors) **SAR441000** mono & with PD1 (solid tumors) **SAR442257** (multiple myeloma/non Hodgkins lymphoma) **SAR444881** (solid tumors) **SAR445419** (acute myeloid leukemia) **SAR443216** (gastric cancer) **SAR443579** (acute myeloid leukemia) **SAR445710** (solid tumors)	**amcenestrant** (metastatic breast cancer 2nd/3rd line) * **amcenestrant** (breast cancer adjuvant) **tusamitamab ravtansine** + ramucirumab (non-small cell lung cancer 2nd/3rd line) **tusamitamab ravtansine** + pembrolizumab (non-small cell lung cancer 1st line) **tusamitamab ravtansine** (exploratory solid tumors) **tusamitamab ravtansine** (gastric cancer) **alomfilimab** (triple negative breast cancer) **SAR444245** (advanced skin cancers) **SAR444245** (head & neck cancers) **SAR444245** (non-small cell lung cancer/ mesothelioma) **SAR444245** (lymphoma) **SAR442720** + KRAS inhibitor (non-small cell lung cancer)	**tusamitamab ravtansine** (non-small cell lung cancer 2nd/3rd line) **amcenestrant + palbociclib** (metastatic breast cancer)
Rare Blood Disorders		**SAR445088** (cold agglutinin disease)	**fitusiran** (hemophilia A&B) **fitusiran** (hemophilia A&B pediatric) **sutimlimab** (cold agglutinin disease) **efanesoctocog alfa** (hemophilia A) **rilzabrutinib** (immune thrombocytopenia)
Immunology & Inflammation	**SAR441566** (inflammatory indications) **SAR444656** (atopic dermatitis) **SAR443726** (atopic dermatitis) **SAR442970** ((inflammatory indications) **SAR443765** ((inflammatory indications) **SAR444336** ((inflammatory indications) **SAR442999** ((inflammatory indications)	**rilzabrutinib** (IgG4 related disease) **rilzabrutinib** (atopic dermatitis) **SAR443122** (cutaneous lupus erythematosus) **SAR444727** (atopic dermatitis) **SAR441344** (Sjogren's syndrome) **SAR441344** (systemic lupus erythematosus) **amlitelimab** (atopic dermatitis)	**itepekimab** (chronic obstructive pulmonary disease)
Neurology	**SAR443820** (amyotrophic lateral sclerosis)	**SAR441344** (multiple sclerosis) **SAR445088** (chronic inflammatory demyelinating polyneuropathy)	**tolebrutinib** (primary progressive multiple sclerosis) **tolebrutinib** (secondary progressive multiple sclerosis) **tolebrutinib** (multiple sclerosis) **tolebrutinib** (myasthenia gravis)
Rare Diseases	**SAR442501** (achondroplasia) **SAR443809** (rare renal diseases)	**venglustat** (Gaucher disease type 3) **venglustat** (Fabry disease) **SAR339375** (Alport syndrome)	**olipudase alfa** (Niemann-Pick disease type B) **Nexviazyme®** (Pompe disease – Infantile onset) **venglustat (**GM2 gangliosidosis)

** Registrational study.*

Phase I studies are the first studies performed in humans, who are mainly healthy volunteers, except for studies in oncology, where Phase I studies are performed in patients. Their main objective is to assess the tolerability, the pharmacokinetic profile (the way the product is distributed and metabolized in the body and the manner by which it is eliminated) and where possible the pharmacodynamic profiles of the new drug (i.e. how the product may react on some receptors).

Phase II studies are early controlled studies in a limited number of patients under closely monitored conditions to show efficacy and short-term safety, and to determine the dose and regimen for Phase III studies.

Phase III studies have the primary objective of demonstrating or confirming the therapeutic benefit and the safety of the new drug in the intended indication and population. They are designed to provide an adequate basis for registration.

a) Oncology

Products in development

Amcenestrant (SAR439859), a selective estrogen receptor degrader (SERD), is being assessed in a pivotal Phase II study (AMEERA-3) in second- and third-line metastatic breast cancer as monotherapy versus physician's choice of single-agent endocrine therapy. A Phase II 14-day window of opportunity study (AMEERA-4) is ongoing in the prior to surgery/neoadjuvant-like setting to inform further development in the adjuvant setting. The evaluation of amcenestrant in combination with palbociclib for the first-line treatment of metastatic breast cancer is also ongoing in a Phase III efficacy study (AMEERA-5). In the prior to surgery/neoadjuvant-like setting, recruitment to the Phase II study (AMEERA-4) was completed in 2021; results will guide further development in the adjuvant setting of breast cancer.

Recruitment of the first patients to the pivotal Phase III study (AMEERA-6) investigating amcenestrant versus tamoxifene in high-risk patients with metastatic breast cancer (adjuvant setting) is expected early 2022.

Tusamitamab ravtansine (SAR408701) is an antibody drug conjugate (ADC) that binds to CEACAM-5, a membrane glycoprotein originally identified as a surface marker on adenocarcinomas of the human gastrointestinal tract. The compound is in Phase III (CARMEN-LC03) for the second- and third-line treatment of metastatic non-squamous non-small cell lung cancer (NSQ NSCLC) with CEACAM-5 positive tumors. In addition, two Phase II studies are ongoing to evaluate the activity of the drug in combination with ramucirumab (CARMEN-LC04) or with pembrolizumab (CARMEN-LC05) in patients with metastatic NSQ NSCLC. In 2021, two Phase II studies were initiated to evaluate tusamitamab ravtansine in patients with CEACAM-5 positive advanced solid tumors (CARMEN-BT01) and in patients with gastric cancer (CARMEN-GC01).

Alomfilimab (SAR445256; formerly Kymab's KY1004) is a fully human IgG1 anti-ICOS antibody with a dual mode-of-action – depleting ICOS high intra-tumoral T regulatory cells and stimulating ICOS low T effector cells – that entered development in 2021 for the treatment of solid tumors in combination with anti-PDL1 treatments (atezolizumab). SAR445256 is currently being investigated in Phase II for triple negative breast cancer (TNBC).

SAR444245 (formerly THOR707) is a non-alpha durably pegylated interleukin-2 (IL-2) acquired from Synthorx in 2020, currently being developed for the treatment of various tumors in monotherapy and combination settings. In 2021, four Phase II trials were initiated for the treatment of advanced skin cancers, head & neck cancers, non-small cell lung cancer/mesothelioma and lymphoma, respectively.

SAR441000 is an immunostimulatory mRNA mixture designed to stimulate both innate and adaptive arms of the immune system to maximize anti-tumor activity. It is developed in collaboration with BioNTech. A First In Human study in patients with advanced melanoma, assessing the safety, PK/PD and anti-tumor activity of SAR441000 as monotherapy and in combination with a PD-1 inhibitor, is ongoing.

SAR442720 is an inhibitor of SHP2 designed to reduce cell growth signaling that is overactive in patients with non-small cell lung cancer and other types of cancers having specific types of genetic mutations. This compound is developed jointly by Sanofi and Revolution Medicines. In 2021, the clinical development strategy was modified to focus on combination with KRAS inhibitors (Phase II study initiated in December 2021) and combination with anti-PD-1 pembrolizumab (Phase I ongoing) in lung cancer.

SAR442257, an anti-CD3/CD28/CD38 trispecific monoclonal antibody, is currently being evaluated in Phase I for the treatment of multiple myeloma/non-Hodgkin lymphoma.

SAR444881, a monoclonal antibody targeting the Ig-like transcript 2 (ILT2) receptor currently being developed with Biond Biologics, entered Phase I in 2021 for the treatment of solid tumors.

SAR445419 (formerly Kiadis' KDS1001) is an off-the-shelf natural-killer (NK) cell therapy with potent killing activity across a broad range of hematologic and solid tumor cell lines in vitro and showing efficacy in various preclinical models alone or in combination with PD-L1 or ADCC potentiating agents. SAR445419 is currently being evaluated in a Phase I study for the treatment of acute myeloid leukemia.

SAR443216 is a trispecific antibody consisting of three distinct target recognition sites, conferring monovalent binding to HER2 (on tumor cells), CD3 (on T cells) and CD28 (a co-receptor for T cell activation), respectively. SAR443216 entered Phase I in 2021 for the treatment of gastric cancer.

SAR443579, an antibody designed to bring a novel mechanism of action by engaging and boosting NK immune cells against Acute Myeloid Leukemia (AML) blasts, is developed with Innate Pharma. SAR443579 entered Phase I in 2021 for the treatment of AML.

SAR445710 (formerly Kadmon's KD033) is an anti PD-L1/IL-15 fusion protein that entered the Sanofi portfolio following the acquisition of Kadmon in December 2021; the product is currently being evaluated in Phase I in patients with solid tumors.

b) Immunology & Inflammation

Itepekimab (SAR440340), a human anti-IL33 monoclonal antibody derived from our alliance with Regeneron, is in Phase III for the treatment of chronic obstructive pulmonary disease in former smokers.

SAR443122, a small molecule against the receptor-interacting serine/threonine-protein kinase 1 (RIPK1), developed in collaboration with Denali, began a Phase II study in 2021 for the treatment of cutaneous lupus erythematosus.

SAR444727, an inhibitor of Bruton's tyrosine kinase that joined the Sanofi portfolio following the acquisition of Principia, is currently in Phase II for the treatment of atopic dermatitis.

Rilzabrutinib (SAR444671) is an inhibitor of Bruton's tyrosine kinase that joined the Sanofi portfolio following the acquisition of Principia in 2020. The development of rilzabrutinib for the treatment of Pemphigus Vulgaris was discontinued in September 2021 based on the Phase III PEGASUS trial results; though the study did not meet its primary or key secondary endpoints, rilzabrutinib's safety profile remained consistent with previous results and no new safety signals were identified. The development of rilzabrutinib is being pursued in other immunological diseases, with two Phase II trials currently ongoing for the treatment of IgG4-related diseases and atopic dermatitis, respectively. Rilzabrutinib is also being evaluated for the treatment of immune thrombocytopenia (see details below in section *e) Rare Blood Disorders*).

Amlitelimab (SAR445229; formerly Kymab's KY1005), an anti-OX40L monoclonal antibody, entered Phase II evaluation in 2021 for the treatment of atopic dermatitis.

SAR441344, an anti-CD40L monoclonal antibody developed in collaboration with Immunext, is being investigated in two Phase II trials for the treatment of Sjogren's syndrome and Systemic lupus erythematosus, respectively. SAR441344 is also being evaluated in multiple sclerosis (see section *c) Neurology*).

SAR441566, the first oral small molecule TNFa inhibitor for the treatment of inflammatory indications, entered Phase I in 2021.

In 2021, four new molecular entities designed with the NANOBODY® technology acquired from Ablynx in 2018 entered Phase I clinical trials for the treatment of immunological diseases:

- **SAR443726** is a bispecific nanobody blocking IL-13 and OX40L, which are key drivers in type 2 inflammatory diseases such as atopic dermatitis;
- **SAR442970** is a bispecific nanobody that combines blockade of TNFa and the immune co-stimulatory regulator OX40L;
- **SAR443765** is a bispecific nanobody targeting TSLP and IL-13;
- **SAR442999** is a bispecific nanobody targeting TNFa and IL-23A, key effector cytokines in inflammatory diseases.

SAR444656 is an IRAK4 degrader, with potential therapeutic application across multiple indications, including atopic dermatitis. SAR444656 is developed in collaboration with Kymera Therapeutics and entered Phase I in 2021.

SAR444336 (formerly known as THOR-809), a pegylated IL-2 designed to selectively engage CD4+ regulatory T cells (and not on effector T or NK cells) which was acquired from Synthorx, entered Phase I in October 2021.

c) Neurology

Tolebrutinib (SAR442168) is an orally administered Bruton's tyrosine kinase (BTK) inhibitor which was designed to access the brain and spinal cord by crossing the blood-brain barrier and impacting immune cell and brain cell signaling. Tolebrutinib is currently being investigated in Phase III studies in relapsing multiple sclerosis, primary progressive multiple sclerosis and non-relapsing secondary progressive multiple sclerosis, respectively. In addition, a Phase III study was initiated in December 2021 for the treatment of Myasthenia Gravis.

SAR441344, an anti-CD40L monoclonal antibody (see section *b) Immunology & Inflammation*), began a Phase II trial in 2021 for the treatment of multiple sclerosis.

A Phase II study evaluating **SAR445088**, a complement C1s inhibitor (see details below in section *e) Rare Blood Disorders*), was initiated in 2021 in patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

SAR443820, a RIPK1 inhibitor developed in collaboration with Denali (formerly known as DNL788) for the treatment of amyotrophic lateral sclerosis, is being investigated in Phase I.

d) Rare Diseases

Nexviazyme® (avalglucosidase alfa) was approved in the USA and in Japan in 2021 for the treatment of patients aged one year and older with late-onset Pompe disease, a rare disease caused by a deficiency of the enzyme acid alpha-glucosidase (GAA). Nexviazyme® is a long-term enzyme replacement therapy targeting the mannose-6-phosphate receptor, the key pathway for cellular uptake of enzyme replacement therapy, to effectively clear glycogen build-up in muscle cells. This approval was based on the Phase III COMET study, which showed clinically meaningful improvements in respiratory function and movement endurance measures. Nexviazyme® is also being investigated in a Phase III study (Baby-COMET) for the treatment of patients aged 6 months or younger who are affected by infantile onset Pompe disease.

On July 27, 2021, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for avalglucosidase alfa for the treatment of people with Pompe disease while considered that avalglucosidase alfa does not qualify as a New Active Substance (NAS). Upon Sanofi's appeal, the CHMP reaffirmed this opinion on November 12, 2021. Sanofi does not agree with the CHMP's conclusion on NAS status and is evaluating potential options for avalglucosidase alfa in the European Union. The CHMP opinion does not constitute a final regulatory decision. The European Commission has 67 days to evaluate the CHMP opinion and render a formal decision. In December 2021, the EMA Committee for Orphan Medicinal Products (COMP) recommended not to maintain the orphan drug designation for avalglucosidase alfa. Sanofi strongly disagrees with the COMP recommendation as it fails to appropriately recognize scientific innovation and does not take into account the totality of the data. An appeal was filed with EMA requesting a re-examination of the COMP Opinion, which can be expected to delay the regulatory decision for avalglucosidase alfa in Europe by several months.

Olipudase alfa is an enzyme replacement therapy targeting the treatment of non-neurological manifestations of acid sphingomyelinase deficiency (ASMD), also known as Niemann-Pick B disease. In 2021, based on the positive results obtained in two separate clinical trials for the treatment of ASMD respectively in the adult (Phase II/III trial ASCEND) and pediatric (Phase I/II trial ASCEND-Peds) populations, olipudase alfa was submitted to regulatory authorities in the USA, Europe, and Japan.

Venglustat (GZ402671) is an orally administered brain penetrant glucosylceramide synthase (GCS) inhibitor that blocks the conversion of ceramide to glucosylceramide (GL-1). Venglustat is currently in development for the treatment of late-onset GM2 gangliosidosis (Tay-Sachs disease and Sandhoff disease), Fabry disease, and Gaucher disease type 3. The clinical program in autosomal dominant polycystic kidney disease (ADPKD) was halted in June 2021 based on the pivotal Phase II/III study (STAGED-PKD), which was declared futile; no safety issue was reported, and significant reduction of GL-1 was observed, confirming the intended mechanism of action of venglustat in lysosomal storage diseases (Fabry disease, Gaucher disease type 3 and GM2 gangliosidosis). Completion of recruitment to the Phase III study in late-onset GM2 gangliosidosis (AMETHIST) is expected early 2022. Positive feedback was received from the FDA at end October 2021 for the initiation of a Phase III trial in patients with Fabry disease. A Phase II study in Gaucher disease type 3 (LEAP) is ongoing.

SAR339375 is a 22-mer non-coding RNA molecule that negatively regulates genes/networks associated with renal epithelial injury and fibrotic diseases, including Alport syndrome for which a Phase II trial (HERA) is ongoing.

SAR442501, an anti-FGFR3 (fibroblast growth factor receptor 3) antibody (Fab format) that directly targets overactive FGFR3 in achondroplasia, is being investigated in a Phase I study.

SAR443809, a humanized monoclonal antibody that selectively inhibits the activated fragment of Factor B (termed Bb) in the alternative pathway of the complement system, entered development (Phase I) in 2021 for the treatment of rare renal diseases.

e) Rare Blood Disorders

Enjaymo™ (sutimlimab; formerly known as BIVV009) is a monoclonal antibody targeting the classical complement pathway (CP) specific serine protease (C1s), thereby inhibiting CP activity which is associated with a variety of immune disorders involving the presence of autoantibodies. Sutimlimab is being developed for the treatment of hemolysis in adult patients with primary cold agglutinin disease (CAD) and has previously received Breakthrough Therapy Designation (BTD) and Orphan Drug Designations (ODD) from the FDA. In October 2021, the FDA accepted the resubmission of the Biologics License Application (BLA) for sutimlimab in CAD. After priority review, the product was approved in February 2022 as the first treatment to decrease the need for red blood cell transfusion due to hemolysis in adults with CAD.

Fitusiran (SAR439774) is a program in collaboration with Alnylam for the development of a siRNA therapeutic agent to treat hemophilia A and B (adults & adolescents, as well as pediatric programs). It uses a novel approach targeting antithrombin (AT), with AT knockdown leading to increase in thrombin generation. Following the revised dose and dosing regimen introduced in the clinical program (ATLAS) in 2021, Sanofi expects that global regulatory submission timelines for the adult and adolescent studies will be delayed by up to approximately 18 months, to 2024, subject to alignment with health authorities.

Efanesoctocog alfa (BIVV001), developed in collaboration with Sobi, is an investigational von Willebrand factor (VWF)-independent factor VIII therapy for people with hemophilia A, designed to potentially extend protection from bleeds with prophylactic dosing of once weekly or longer. Efanesoctogog alfa received Fast Track Designation from the FDA in February 2021 and is currently being investigated in the pivotal Phase III study (EXTEND-1) in patients with severe hemophilia A older than 12 years of age. A Phase III study (EXTEND-Kids) evaluating efanesoctocog alfa in pediatric patients younger than 12 years of age was initiated in March 2021.

Rilzabrutinib (SAR444671) is being investigated in a Phase III trial (LUNA 3; initiated in April 2021) for the treatment of immune thrombocytopenia (ITP) in adults and adolescents, for which the FDA has granted Fast Track Designation.

SAR445088 is a humanized IgG4 monoclonal antibody that binds to and inhibits C1s, thereby inhibiting classical pathway (CP) of complement activity. Activation of the CP of complement is associated with a variety of immune disorders involving the presence of autoantibodies. Inhibition of autoantibody-mediated CP activation on the surface of erythrocytes via C1s binding prevents complement opsonin deposition on red blood cells and protects them from phagocytosis and extravascular hemolysis in autoimmune hemolytic anemia such as cold agglutinin disease (CAD); SAR445088 is currently under evaluation in a Phase II study in this indication. The development of the product for the treatment of immune thrombocytopenic purpura was discontinued in 2021.

f) Line extensions

Libtayo® (cemiplimab), a monoclonal antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1), was approved in 2021 for the treatment of metastatic or locally advanced basal cell carcinoma (BCC) and for the first-line treatment of patients with advanced non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression. Libtayo® is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

Libtayo® was filed for label extensions with the FDA and he EMA for second-line treatment of cervical cancer. On January 27, 2022, Sanofi and Regeneron announced the voluntary withdrawal of the supplemental Biologics License Application.

A supplemental Biologics License Application (sBLA) was submitted to the FDA in November 2021 for Libtayo® in chemotherapy combination in first-line NSCLC. Libtayo® was submitted to the EMA in the same indication in December 2021.

Sarclisa® (isatuximab), a monoclonal antibody designed to selectively bind to CD38, a cell surface antigen expressed in multiple myeloma (MM) cancer cells and other hematological malignancies, is marketed in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

In March 2021, the FDA approved Sarclisa® in combination with carfilzomib and dexamethasone for the treatment of adult patients with RRMM who have received one to three prior lines of therapy. Sarclisa® was approved by the European Commission in April 2021 for the treatment of adult patients with multiple myeloma (MM) who have received at least one prior therapy. These approvals were based on the results of the IKEMA Phase III clinical trial.

Sarclisa® continues to be evaluated in combination with current standard and novel treatments across the MM treatment continuum:

- the Phase III IMROZ trial is a randomized, open-label, multicenter study assessing the clinical benefit of Sarclisa® in combination with bortezomib (Velcade®), lenalidomide (Revlimid®) and dexamethasone versus bortezomib, lenalidomide and dexamethasone in patients with newly diagnosed MM not eligible for transplant;
- the Phase III GMMG HD7 trial is a randomized, open-label, multicenter study assessing the clinical benefit of Sarclisa® in combination with lenalidomide, bortezomib, and dexamethasone for induction and with lenalidomide for maintenance in patients with newly diagnosed MM. This study is being conducted in collaboration with the German-speaking Myeloma Multicenter Group (GMMG);
- the Phase III ITHACA trial is a randomized, open-label, multicenter study assessing Sarclisa® in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone in patients with high-risk smoldering MM; and
- Phase I studies are ongoing to evaluate Sarclisa® in new combinations with emerging novel mechanisms of action in patients with RRMM or in newly diagnosed MM patients.

Sarclisa® is also under investigation in several early phase studies for the treatment of hematologic malignancies and other hematologic indications:

- a registrational Phase II study assessing the antitumor activity, safety, and pharmacokinetics of isatuximab in combination with chemotherapy in pediatric patients with relapsed/refractory B or T acute lymphoblastic leukemia or acute myeloid leukemia in first or second relapse; and
- a Phase II study evaluating the safety, pharmacokinetics, and efficacy of subcutaneous isatuximab in adults with warm autoimmune hemolytic anemia (wAiHA).

Dupixent® (dupilumab), an interleukin-4 receptor alpha antagonist, is a human monoclonal antibody of the IgG4 subclass that binds to the IL-4Ra subunit and inhibits IL-4 and IL-13 signaling. Dupixent® is being jointly developed with Regeneron in several indications:

- **atopic dermatitis:** the product was approved in China in September 2021 for adolescents aged 12-17 years with moderate-to-severe atopic dermatitis. Further to the positive results of the pivotal trial evaluating Dupixent® for the treatment of children aged 6 months to 5 years with moderate-to-severe atopic dermatitis, the product was submitted in the USA in December 2021;
- **asthma:** Dupixent® was approved in the US in October 2021 for the pediatric population aged 6 to 11 years;
- **eosinophilic esophagitis:** the results of the Phase III clinical program will be available in 2022; *see B.2. Main pharmaceutical products.* We intend to submit this product to the FDA for this indication in the first quarter of 2022;
- **adjunct to immunotherapy:** a proof-of-concept study to evaluate Dupixent® as an adjunct to immunotherapy (peanut allergy) is ongoing;
- **multiple Phase III studies in the following indications were ongoing in 2021:**
  - chronic obstructive pulmonary disease,
  - chronic spontaneous urticaria,
  - prurigo nodularis,
  - chronic rhinosinusitis without nasal polyps,
  - bullous pemphigoid,
  - chronic inducible cold urticaria, and
  - allergic fungal rhinosinusitis.

Kevzara® (sarilumab) is a monoclonal antibody against the Interleukin-6 Receptor derived from our alliance with Regeneron, and is already marketed in the treatment of moderate to severe rheumatoid arthritis. The product is currently being evaluated in a pivotal Phase IIb study in pediatric populations for two indications: polyarticular juvenile idiopathic arthritis and systemic juvenile idiopathic arthritis.

Aubagio® (teriflunomide), an immunomodulatory agent with anti-inflammatory properties that selectively and reversibly inhibits the mitochondrial enzyme dihydroorotate dehydrogenase (DHO-DH) already marketed for the treatment of relapsing forms of multiple sclerosis and relapsing remitting multiple sclerosis, was approved in the European Union in 2021 for treatment of the pediatric population (aged 10 to 17 years).

Cerdelga® (eliglustat), a potent, highly specific ceramide analog inhibitor of GL-1 synthesis already marketed for Gaucher disease type 1 in adult patients, is currently in Phase III for the treatment of Gaucher disease type I in pediatric patients; *see B.2. Main pharmaceutical products*.

B.5.2. Vaccines

The Vaccines R&D portfolio includes 10 projects in advanced development (including one monoclonal antibody candidate), as shown in the table below. The portfolio includes four projects for novel targets and six enhancements of existing vaccines. Updates to the programs in 2021 are described below.

For strategic reasons, Sanofi Pasteur has decided to terminate the development of a COVID-19 mRNA vaccine candidate.

Phase I	Phase II	Phase III	Registration
		Nirsevimab, mAb[(a)] Passive prevention of respiratory syncytial virus infections in all infants	Shan6 DTwP-HepB-Polio-Hib[(b)] Pediatric hexavalent vaccine
	21-valent Pneumo Conjugate Vaccine (PCV21)[(a)] Prevention of pneumococcal disease	MenQuadfi® Advanced generation meningococcal ACYW conjugate vaccine US / EU infants aged 6 weeks & older	
	Respiratory Syncytial Virus (RSV) vaccine (PhI/II) Prevention of RSV infections in toddlers aged 6 months & older	VRVg Purified vero rabies vaccine	
	Vero Yellow Fever vaccine (vYF)	COVID-19 recombinant adjuvanted[(a)] vaccine (Phase I/II) Prevention of novel Coronavirus	
		Fluzone® QIV HD Quadrivalent inactivated influenza vaccine – High dose for pediatric use	
	Meningococcal B Vaccine Prevention of invasive disease caused N. Meningitidis Serogroup B		

(a) Partnered and/or in collaboration: Sanofi may have limited or shared rights to some of these products.
(b) Hib = Hemophilus influenzae type b.

Enhancements of existing vaccines

Fluzone®: QIV HD is a higher dose quadrivalent influenza vaccine licensed in the US and in Europe for the elderly population, who do not respond as well to standard-dose influenza vaccines due to aging of the immune system (immuno-senescence). A Phase III trial is ongoing to evaluate safety and efficacy in the pediatric population.

Shan6™ is a cost-effective, all-in-one liquid hexavalent combination vaccine being developed for low and middle income countries (WHO pre-qualification). It comprises detoxified whole-cell pertussis as well as diphtheria toxoid, tetanus toxoid, Hemophilus influenza type b PRP-T, inactivated poliovirus types 1, 2, and 3 and hepatitis B virus components. In May 2021, Sanofi Pasteur obtained Indian regulatory approval for Shan6™, and also submitted the file for WHO pre-qualification.

MenQuadfi®: Sanofi Pasteur's Men ACYW-TT vaccine is our latest advance in meningococcal quadrivalent conjugate vaccination, designed to help protect an expanded patient group including infants and adolescents through older adults. MenQuadfi® is already licensed in the US (for people aged 2 years and over), and in Europe and several other countries (for people aged 12 months and over). Additional Phase III trials are ongoing to evaluate immunogenicity and safety in infants aged 6 weeks and older. In May 2021, a request was submitted to the WHO for pre-qualification of MenQuadfi® for people aged 12 months and older. In September 2021, the MenQuadfi® dossier was submitted in Japan. Marketing approval is pending in numerous other countries.

Meningococcal Group B (Men B): This vaccine candidate is intended to provide active immunization against invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B (Men B) for all age groups, targeting increased breadth of protection and enhanced tolerability compared to currently marketed Men B products. A Phase I/II study was initiated In March 2021. Early-stage development studies are under way to combine the four meningococcal serogroups represented in MenQuadfi® with Men B to advance a pentavalent meningococcal vaccine candidate.

Rabies Vaccine: A next-generation purified human rabies vaccine (VRVg) is under development, aimed at replacing both of Sanofi Pasteur's currently commercialized rabies vaccines (Imovax® Rabies and Verorab®). It will be cultured on Vero cells and will be free of animal or human material. VRVg is currently in Phase III trials in order to support pre and post exposure indications.

Vero Yellow Fever (vYF) vaccine candidate is a next generation freeze-dried live-attenuated yellow fever vaccine produced on a Vero cell line, for subcutaneous and intra-muscular administration in people aged nine months and older. This vaccine aims to replace Stamaril® and YF-VAX® with a single product. In January 2020, the first Phase I/II trial was initiated in the US. In July 2021, we started Phase II trials of this yellow fever vaccine candidate.

Novel targets

Nirsevimab is a monoclonal antibody engineered to have a long half-life, so that only one dose would be needed for the entire respiratory syncytial virus (RSV) season to provide passive immunity and prevent RSV infection in all infants for their first RSV season (and in high-risk infants, for their first and second RSV seasons). Sanofi Pasteur has an agreement with AstraZeneca to develop and commercialize nirsevimab. Positive primary analysis of the Phase IIb trial, published in the New England Journal of Medicine in July 2020, demonstrated the safety and efficacy of nirsevimab. The Phase III MELODY study, initiated in 2019, achieved its primary endpoint of protection against medically attended RSV lower respiratory tract infection in healthy full-term and late pre-term infants. The MEDLEY Phase II/III study, conducted in preterm infants and infants with chronic lung disease or congenital heart disease, showed positive safety and pharmacokinetics when compared to standard of care. Regulatory submissions are expected to begin in 2022. Nirsevimab received fast-track designation from the FDA in 2015, and FDA Breakthrough Therapy designation in February 2019, and was granted PRIME eligibility by the EMA in February 2019. It has been selected by the Japanese Agency for Medical Research and Development as a priority medicine, and received breakthrough therapy designation in China in January 2021. We initiated a Phase III study in China in November 2021.

RSV toddler vaccine: Sanofi Pasteur has a Cooperative Research and Development Agreement (CRADA) with the US National Institute of Health (NIH) to develop a live attenuated RSV vaccine for immunization of infants aged 6 months and older. We initiated the Phase I/II study in the US in September 2020. This trial is evaluating the safety and effectiveness of two doses of an intranasal delivery device in infants, the goal being to extend the immunity offered by nirsevimab to additional RSV seasons.

Pneumococcal Conjugate Vaccine (PCV): Sanofi Pasteur is collaborating with SK Chemicals (South Korea) to develop a 21-valent pneumococcal conjugate vaccine that will provide expanded protection against pneumococcal disease globally in at risk populations and in different age groups. This vaccine entered Phase II in May 2020. Phase II studies in adult, toddler and infant populations are ongoing.

Recombinant adjuvanted COVID-19 vaccine candidate: this vaccine candidate is produced in the baculovirus expression system in SF9 cells, and is intended for use in active immunization for the prevention of COVID-19 (SARS-CoV-2) in a pandemic setting. This candidate is being developed in partnership with GlaxoSmithKline (GSK), as it uses GSK's adjuvant. The Coronavirus (COVID-19) vaccine program entered the Sanofi Pasteur portfolio in March 2020 and entered Phase I/II in September 2020. A new Phase II study was initiated with an improved antigen formulation in February 2021, with support from the US Biomedical Advanced Research and Development Authority (BARDA). A Phase III trial started in the second quarter of 2021 to demonstrate vaccine efficacy using both monovalent and bivalent vaccine formulations. The continued emergence of new variants of concern and waning immunity mean there will be an important worldwide need for booster vaccinations; in parallel with the Phase III efficacy study, Sanofi Pasteur launched a comprehensive study to evaluate the vaccine as a heterologous booster for people initially vaccinated with Emergency Use Authorization (EUA) vaccines. In mid-December 2021, positive preliminary booster data were communicated, showing that neutralizing antibodies increased across all primary vaccines received (mRNA or adenovirus) with a good safety and immunogenicity profile. We will file booster data with the regulatory authorities after the Phase III results.

B.5.3. R&D Expenditures for late stage development

Expenditures on research and development amounted to €5,692 million in 2021 (€5,530 million in 2020), comprising €4,330 million in the Pharmaceuticals segment; €153 million in the Consumer Healthcare segment; €712 million in the Vaccines segment; and €497 million

allocated to "Other", representing the R&D support function. Research and development expenditures represented approximately 15.1% of our net sales in 2021, compared with approximately 15.3% in 2020.

The increase in R&D expenditures in 2021 was mainly due to additional investments in Immunology and Oncology, while cost control efforts continue. Preclinical research expenditures in the Pharmaceuticals segment amounted to €718 million in 2021, compared with €775 million in 2020. This reduction mainly relates to the termination of the immuno-oncology discovery agreement with Regeneron. Clinical development expenditure in the Pharmaceuticals segment amounted to €3,612 million in 2021; the majority of this covered Phase III and post-marketing studies, reflecting the cost of monitoring large-scale clinical trials.

B.6. Markets

A breakdown of revenues by business segment and by geographical region for 2021, 2020, and 2019 can be found at Note D.35. to our consolidated financial statements, included at Item 18. of this annual report.

The following market shares and ranking information are based on consolidated national pharmaceutical sales data (excluding vaccines), in constant euros, on a September 2021 MAT (Moving Annual Total) basis. The data are mainly from IQVIA local sales audit supplemented by various other country-specific sources including Knobloch (Mexico), GERS (France) and HMR (Portugal).

B.6.1. Marketing and distribution

We have business operations in approximately 90 countries and our products are available in more than 170 countries. A breakdown of our aggregate net sales by geographical region is presented in "Item 5. Operating and Financial Review and Prospects — Results of Operations — Year Ended December 31, 2021 Compared with Year Ended December 31, 2020." Sanofi is the eighth largest pharmaceutical company globally by sales. Our main markets in terms of net sales are respectively:

- United States: we rank twelfth with a market share of 3.6%;
- Europe: we are the fourth largest pharmaceutical company in France where our market share is 5.8%, and we rank seventh in Germany with a 3.3% market share; and
- other countries: we are ranked nineteenth in Japan with a market share of 1.8%, and twelfth in China with a market share of 1.6%.

Although specific distribution patterns vary by country, we sell prescription drugs primarily to wholesale drug distributors, independent and chain retail drug outlets, hospitals, clinics, managed-care organizations and government institutions. Rare diseases products are also sold directly to physicians. With the exception of Consumer Healthcare products, our drugs are ordinarily dispensed to patients by pharmacies upon presentation of a doctor's prescription. Our Consumer Healthcare products are also sold and distributed through e-commerce, which is a growing trend in consumer behavior. Our vaccines are sold and distributed through multiple channels including physicians, pharmacies, hospitals, private companies and distributors in the private sector, and governmental entities and non-governmental organizations in the public and international donor markets.

We use a range of channels from in-person to digital to disseminate information about and promote our products among healthcare professionals, ensuring that the channels not only cover our latest therapeutic advances but also our established prescription products, which satisfy patient needs in some therapy areas. We regularly exhibit at major medical congresses. In some countries, products are also marketed directly to patients by way of television, radio, newspapers and magazines, and digital channels (such as the internet). National education and prevention campaigns can be used to improve patients' knowledge of their conditions.

Our sales representatives, who work closely with healthcare professionals, use their expertise to promote and provide information on our drugs. They represent our values on a day-to-day basis and are required to adhere to a code of ethics and to internal policies in which they receive training.

Although we market most of our products through our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographical areas. Our major alliances are detailed at "Item 5. Operating and Financial Review and Prospects — Financial Presentation of Alliances." See also "Item 3. Key Information — D. Risk Factors — We rely on third parties for the discovery, manufacture and marketing of some of our products."

B.6.2. Competition

The pharmaceutical industry continues to experience significant changes in its competitive environment.

There are four types of competition in the prescription pharmaceutical market:

- competition between pharmaceutical companies to research and develop new patented products or address unmet medical needs;
- competition between different patented pharmaceutical products marketed for the same therapeutic indication;
- competition between original and generic products or between original biological products and biosimilars, at the end of regulatory exclusivity or patent protection; and
- competition between generic or biosimilar products.

Generics manufacturers who have received all necessary regulatory approvals for a product may decide to launch a generic version before the patent expiry date, even in cases where the owner of the original product has already commenced patent infringement litigation against the generics manufacturer. Such launches are said to be "at risk" for the promoter of the generic product because it may be required to pay damages to the owner of the original product in the context of patent infringement litigation; however, such launches may also significantly impair the profitability of the pharmaceutical company whose product is challenged.

Drug manufacturers also face competition through parallel trading, also known as reimportation. This takes place when drugs sold abroad under the same brand name as in a domestic market are imported into that domestic market by parallel traders, who may repackage or resize the original product or sell it through alternative channels such as mail order or the internet. This situation is of particular relevance to the EU, where such practices have been encouraged by the current regulatory framework. Parallel traders take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices.

Finally, pharmaceutical companies face illegal competition from falsified drugs. The WHO estimates that falsified products account for 10% of the market worldwide, rising to 30% in some countries. All therapeutic areas are affected, also including vaccines. However, in markets where powerful regulatory controls are in place, falsified drugs are estimated to represent less than 1% of market value.

The same types of competition apply in Consumer Healthcare, except that in this business there are two types of generic products: private labels and store brands.

In Vaccines, there are two types of competition:

- competition between vaccine companies to research and develop new patented products or address unmet medical needs; and
- competition between different patented (or non-patented) vaccine products marketed for the same therapeutic indication.

Generics and biosimilars are not an issue in vaccines at present, since vaccines are still mostly produced from proprietary viral or bacterial strains. As with pharmaceutical drugs, vaccine manufacturers can face competition through parallel trading. However, the extent of such practices is limited by the need for cold chain distribution of vaccines, and by the fact that vaccines are sold and administered through pharmacies or dispensing physicians.

B.6.3. Regulatory framework

The pharmaceutical and health-related biotechnology sectors are highly regulated. National and supranational health authorities administer a vast array of legal and regulatory requirements that dictate pre-approval testing and quality standards to maximize the safety and efficacy of a new medical product. These authorities also regulate product labeling, manufacturing, importation/exportation and marketing, as well as mandatory post-approval requirements and commitments.

The submission of an application to a regulatory authority does not guarantee that a license to market will be granted or that a product will be approved. Furthermore, each regulatory authority may impose its own requirements during product development or during the application review. It may refuse to grant approval or require additional data before granting approval, even though the same product has already been approved in other countries. Regulatory authorities also have the authority to request product recalls and product withdrawals, and to impose penalties for violations of regulations.

Product review and approval can vary from six months or less to several years from the date of application submission depending upon the country and regulatory jurisdiction. Factors such as the quality of data and evidence, the review procedures, the nature of the product and the condition to be treated, play a major role in the length of time a product is under review.

In the EU, there are three main procedures for applying for marketing authorization:

- the centralized procedure is mandatory for drugs derived from biotechnologies; new active substances designed for human use to treat HIV, viral diseases, cancer, neurodegenerative diseases, diabetes and auto-immune diseases; orphan drugs; and innovative products for veterinary use. When an application for human use is submitted to the EMA, the scientific evaluation of the application is carried out by the Committee for Medicinal Products for Human Use (CHMP) and a scientific opinion is prepared. This opinion is sent to the European Commission, which adopts the final decision and grants an EU marketing authorization. Such a marketing authorization is valid throughout the EU, and the drug may be marketed within all EU Member States;
- if a company is seeking a national marketing authorization in more than one Member State, two procedures are available to facilitate the granting of harmonized national authorizations across Member States: the mutual recognition procedure or the decentralized procedure. Both procedures are based on the recognition by national competent authorities of a first assessment performed by the regulatory authority of one Member State;
- national authorizations are still possible, but are only for products intended for commercialization in a single EU Member State or for line extensions to existing national product licenses.

In the EU, vaccines are treated as pharmaceutical products, and therefore have to obtain marketing authorization under the centralized procedures described above.

Generic products are subject to the same marketing authorization procedures. A generic product must contain the same active medicinal substance as a reference product approved in the EU. Generic applications are abridged: generic manufacturers only need to submit quality data and demonstrate that the generic drug is “bioequivalent” to the originator product (i.e., performs in the same manner in the patient’s body), but do not need to submit safety or efficacy data since regulatory authorities can refer to the reference product’s dossier.

Another relevant aspect in the EU regulatory framework is the “sunset clause” under which any marketing authorization ceases to be valid if it is not followed by marketing within three years, or if marketing is interrupted for a period of three consecutive years.

In the US, applications for pharmaceutical approval and biological product licensure are submitted for review to the FDA, which has broad regulatory jurisdiction over all pharmaceutical and biological products that are intended for sale and marketing in the US. To commercialize a product in the US, a new drug application (NDA) under the Food, Drug and Cosmetic (FD&C) Act, or a Biological License Application (BLA) under the Public Health Service (PHS) Act, must be submitted to the FDA for filing and pre-market review. Specifically, the FDA must decide whether the product is safe and effective for its proposed use; if the benefits of the product outweigh its risks; whether the product labeling is adequate; and if the manufacturing of the product and the controls used for maintaining quality are adequate to preserve the product's identity, strength, quality and purity. Based upon this review, the FDA can stipulate post-approval

commitments and requirements. Changes to an approved product, including but not limited to a new indication, require submission of a supplemental NDA (sNDA) for a drug or a supplemental BLA (sBLA) for a biological product.

Sponsors wishing to market a generic drug can file an Abbreviated NDA (ANDA) under 505(j) of the FD&C Act. These applications are "abbreviated" because they are generally not required to include data to establish safety and efficacy but need to demonstrate that their product is bioequivalent (i.e., performs in humans in the same manner as the originator's product) to a reference product. Consequently, the length of time and cost required for development of generics can be considerably less than for the innovator's drug. The ANDA pathway in the US can only be used for generics of drugs that can be referenced as having been approved under the FD&C Act.

The FD&C Act provides another option for NDA product approval via the 505(b)(2) pathway. This 505(b)(2) application contains full reports of investigations of safety and effectiveness but at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, under the 505(b)(2) pathway an applicant may seek to rely on literature or earlier FDA findings of safety and effectiveness for approved drugs. Similarly, under the PHS Act, there is an abbreviated licensure pathway for biological products shown to be biosimilar (highly similar with no clinically meaningful differences) or interchangeable with an FDA-licensed reference BLA product.

In Japan, the entire process of approval review from review-related inspections and clinical trial consultation to review for the drugs approved by the Ministry of Health, Labour and Welfare (MHLW) is undertaken by the Pharmaceuticals and Medical Devices Agency (PMDA). The PMDA conducts first scientific review of the NDA submitted, assessing particularly the safety, efficacy and quality of the product or medical device proposed. Results of this primary evaluation are then submitted to the PMDA's external experts. After a second evaluation based on the external experts' feedback, a report is provided; the Pharmaceutical Affairs and Foods Sanitation Council (PAFCS) – one of the councils organized under the J-MHLW as advisory commission – is consulted, and advises the MHLW on final approvability.

For Japanese registrations, clinical data for Japanese patients are necessary. The regulatory authorities can require local clinical studies, though they also accept multi-regional studies including Japan. In some cases, bridging studies have been conducted to verify extrapolability of foreign clinical data to Japanese patients and to obtain data to determine the appropriateness of the dosages for Japanese patients.

The MHLW may require additional post-approval studies (Phase IV) for some specific cases, to further evaluate safety and/or to gather information on the use of the product under specified conditions. In approval of new drugs, new indications, new dosages or new administrations, the re-examination period is determined by the MHLW. Post-marketing information on a drug for the predetermined period after approval is collected to reconfirm its efficacy, safety and quality at the end of the period. This collection process involves both post-marketing surveillance (PMS), which is a non-interventional study, and post-marketing clinical trials.

For generic products, the data necessary for filing are similar to EU and US requirements. Companies only need to submit quality data, and data demonstrating bioequivalence to the originator product, unless the drug is biopharmaceutical. Common Technical Document (CTD) submission for generics has been mandatory since March 2017.

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) was created in 1990 and reformed in 2015.

The ICH currently includes 18 Members and 33 Observers. Harmonization is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side.

In addition to the joint efforts, Free Trade Agreements (FTAs) have proven to be one of the best ways to open up foreign markets to exporters and to allow for discussions on harmonization topics for regulatory authorities. Some agreements, such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), are international in nature, while others are between specific countries. The requirements of many countries (including Japan and several EU Member States) to negotiate selling prices or reimbursement rates for pharmaceutical products with government regulators significantly extend the time to market entry beyond the initial marketing approval. While marketing authorizations for new pharmaceutical products in the EU have been largely centralized within the European Commission in collaboration with the EMA, pricing and reimbursement remain a matter of national competence.

B.6.4. Pricing & reimbursement

We are operating in an increasingly complex and rapidly evolving market access environment, with continued downward price pressure and facing unprecedented challenges due to the global COVID-19 pandemic.

At a time of intense scrutiny on drug pricing across major markets, governments and payers are using increasingly restrictive price control policies. The mechanisms used vary from country to country, and include price referencing for imported drugs, increased patient co-payments, restrictive formularies, prescribing guidelines, tendering procedures, generic and biosimilar substitution, and medico-economic evaluations of healthcare products.

In addition, pharmaceutical companies are expected to continuously demonstrate value throughout the product life cycle (such as through comparative efficacy studies, real-world patient data, and budget modelling). This requires vast amounts of data and scientific evidence, raising the bar for market entry, with significant variations from country to country.

In response to strong budgetary pressures, there has been a growing payer interest in new payment models based on risk-sharing and outcomes, with a view to balance drug costs and patient access to innovation. Despite implementation challenges, new performance-based and outcome-based deals are gaining traction in a growing number of markets.

We expect these trends will continue in 2022 and beyond, potentially accelerated or exacerbated by the COVID-19 crisis.

United States

Overview of the US health insurance system:

Commercial insurance is offered widely as part of employee benefit packages and is the main source of access to subsidized healthcare provision. Some individuals purchase private health plans directly, while publicly subsidized programs provide cover for retirees, the poor, the disabled, uninsured children, and serving or retired military personnel. Double coverage can occur.

Commercial insurance includes:

- Managed Care Organizations (MCOs), combine the functions of health insurance, delivery of care, and administration. MCOs use specific provider networks and specific services and products. There are three types of managed care plans: Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), and Point of Service (POS) plans;
- Pharmacy Benefit Managers (PBMs), serve as intermediaries between insurance companies, pharmacies and manufacturers to negotiate rebates and discounts on formulary placement for commercial health plans, self-insured employer plans, Medicare Part D plans, and federal and state government employee plans.

Government insurance includes:

- Medicare, which provides health insurance for retirees and for people with permanent disabilities. The basic Medicare scheme (Part A) provides hospital insurance only, and the vast majority of retirees purchase additional cover through some or all of three other plans named Part B, Part C and Part D. Part D enables Medicare beneficiaries to obtain outpatient drug coverage. Almost two-thirds of all Medicare beneficiaries have enrolled in Part D plans;
- Medicaid, which provides health insurance for low-income families, certain qualified pregnant women and children, individuals receiving supplemental security income, and other eligible persons determined on a state-by-state basis.

In the US there is still uncertainty about the evolution and impact of the COVID-19 pandemic as well as the pace of implementation of drug pricing reforms. The federal government is poised to exert greater price controls in the mid to longer term, which would likely have a significant negative impact on US biopharma that are as yet difficult to estimate.

The Biden Administration also seeks to encourage enforcement of price transparency in healthcare at the federal and state level. New public disclosure requirements for hospitals, insurers and health plans are contained in the Transparency in Coverage Rule issued by the Centers for Medicare and Medicaid Services (CMS) in October 2020. In addition, more than half of US states have passed or are pursuing laws to bring greater transparency and prevent price gouging – an issue that has led to intense debate on insulin costs in recent years.

Despite slow uptake to date, biosimilar adoption is likely to accelerate with first interchangeable biosimilars recently approved by the US FDA for Lantus® (insulin glargine) and Humira® (adalimumab). Savings are projected to potentially exceed $100 billion over the next five years, according to IQVIA. However, the impact of interchangeability on biosimilar uptake and pricing remains to be seen in the long term.

Moreover, the continued consolidation in the commercial health insurance market is expected to exert greater pricing pressure. With the three largest Group Purchasing Organizations (GPOs) OptumRx (Emisar), CVS/Caremark (Zinc), and Express Scripts (Ascent) – now covering over 85% of US prescription claims, consolidation has led to more aggressive formulary management of specialty medicines and larger rebates in return for access. The rise of drug formulary exclusions, in favor of lower-cost therapeutic alternatives, may result in a significant reduction in sales.

China

China has embarked on a vast program of reforms over the past decade towards the Healthy China 2030 vision. Healthcare is one of the growth priorities under the country's 14th Five-Year Plan (2021-2025), with policies aimed at addressing a large and increasing burden of disease (especially cancer, diabetes and cardiovascular diseases), while balancing costs and innovation.

We plan to launch 25 innovative vaccines and medicines in the Chinese market by 2025 under existing accelerated approval pathways (for treatments with urgent clinical needs). For example, Dupixent® received approval for the treatment of adults with moderate-to-severe atopic dermatitis in June 2020, within 6 months of filing through an expedited review process.

However, pricing and access challenges are expected to intensify in the years to come as the country faces slower growth and rising healthcare costs. A growing number of our products have a chance to undertake national reimbursement drug list (NRDL) negotiations where the lowest price prevails in order to compete with domestic companies, as in the case of national volume-based procurement (VBP) tenders.

Since 2017, annual updates of the National Reimbursement Drug List (NRDL) have improved access and affordability for innovative therapies in exchange for steep price cuts. According to the Chinese National Healthcare Security Administration (NHSA), 67 new medicines were added to the NRDL through negotiation in December 2021, including Praluent® and a number of drugs for rare diseases, with an average price reduction of 62%, higher than in previous years (54% in 2020, 61% in 2019). Importantly, for the second consecutive year, imported PD-1 inhibitors remain excluded in favor of domestically developed treatments – signaling the growing footprint of Chinese biotechs in NDRL listing, particularly in the crowded and highly competitive PD-1/PD-L1 – inhibitor market.

The volume-based procurement (VBP) policy has also expanded rapidly, placing downward price pressure on our established products portfolio. Sanofi actively participated in the three national procurement rounds implemented in 2021, and won successive tenders for schizophrenic treatment amisulpride (February) and oxiloplatin 50 mg (June), as well as for our insulins Toujeo® and Lantus® (November) during the first national biologic VBP. Meanwhile, as in previous rounds, Chinese pharmaceutical companies won the majority of the bids due to their ability to drastically reduce production costs.

Europe

The economic and financial crisis triggered by the COVID-19 pandemic has had, and continues to have, a major (though varying) negative impact on many European healthcare systems. Governments have responded with a wide range of interventions to tackle increased budgetary pressures and other constraints.

At a time of great financial instability, the crisis has exacerbated the effect of existing cost-containment mechanisms, which are already widely established across Europe. These include price referencing, deeper discounting in tenders and renegotiating contracts, and further substitution of generics and biosimilars.

The pandemic has also created an impetus for centralized procurement approaches to vaccines and medicines at EU level. Various cross-border alliances have already emerged in recent years such as the Valletta Declaration Group, the BeNeLuxA initiative, the Nordic Council and the Visegrad Group, with the potential to exert greater bargaining power in pricing and access negotiations.

The European Commission (EC) has committed to enhanced pan-European cooperation on health technology assessment (HTA). After years of joint work between Member States, the new EU HTA regulation was adopted on December 13, 2021 and will be implemented in a staged process by 2025. Under the new rules, Member States will be cooperating on conducting future joint clinical assessments and joint scientific consultations.

The adoption of the EU HTA Regulation will contribute to the objectives of the new Pharmaceutical Strategy for Europe towards improving patient access to innovative and affordable medicines. However, the potential future directions of that strategy – and in the near term, changes to regulations on pediatric and orphan drugs – are a growing cause of concern, since they could be detrimental to existing incentive mechanisms that favor innovation.

Similar pressures are being felt in other regions and countries around the globe.

To address the multiple challenges mentioned above, we are continuously adapting our pricing and market access strategies to country-specific requirements, as well as piloting and developing new innovative contracting models with payers and new digital solutions.

B.7. Patents, intellectual property and other rights

B.7.1. Patents

Patent protection

We own a broad portfolio of patents, patent applications and patent licenses worldwide. These patents are of various types and may cover: active ingredients; pharmaceutical formulations; product manufacturing processes; intermediate chemical compounds; therapeutic indications/methods of use; technology platforms; delivery systems; digital applications; and enabling technologies, such as assays.

Patent protection for individual products typically extends for 20 years from the patent filing date in countries where we seek patent protection. A substantial part of the 20-year life span of a patent on a new molecule (small molecule or biologic) has generally already passed by the time the related product obtains marketing authorization. As a result, the effective period of patent protection for an approved product's active ingredient is significantly shorter than 20 years. In some cases, the period of effective protection may be extended by procedures established to compensate regulatory delay in Europe (via Supplementary Protection Certificate or SPC), in the US (via Patent Term Extension or PTE), and in Japan (PTE).

The protection a patent provides to the related product depends upon the type of patent and its scope of coverage, and may also vary from country to country.

In Europe, applications for new patents may be submitted to the European Patent Office (EPO). A European Patent (EP) application may cover the 38 European Patent Convention Member States, including all Member States of the EU. The granted EP establishes corresponding national patents with uniform patent claims among the Member States.

In 2013, EU legislation was adopted to create a European Unitary Patent and a Unified Patent Court. However, it will only enter into force once the agreement on the Unified Patent Court is fully ratified by Germany. As of the date of this document, 16 countries including France have ratified the agreement.

We monitor our competitors and vigorously seek to challenge patent infringers when such infringement would negatively impact our business objectives. See "Item 8. — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings — Patents" of this annual report.

The expiration or loss of a patent covering a new molecule, typically referred to as a compound patent, may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product (see "Item 3. Key Information — D. Risk Factors"). In some cases, it is possible to continue to benefit from a commercial advantage through product manufacturing trade secrets or other types of patents. Certain categories of products, such as traditional vaccines and insulin, were historically relatively less reliant on patent protection and may in many cases have no patent coverage. It is nowadays increasingly frequent for novel vaccines also to be patent protected.

Regulatory exclusivity

In some markets, including the EU and the US, many of our pharmaceutical products may also benefit from multi-year regulatory exclusivity periods, during which a generic or biosimilar competitor may not rely on our clinical trial and safety data in its drug application. This exclusivity operates independently of patent protection and may protect the product from generic competition even if there is no patent covering the product.

In the US, the FDA will not grant final marketing authorization to a generic competitor for a New Chemical Entity (NCE) until the expiration of the regulatory exclusivity period (five years) that commences upon the first marketing authorization of the reference product. Significant line extensions of existing NCEs may qualify for an additional three years of regulatory exclusivity if certain conditions are met. In the US, a

different regulatory exclusivity period applies to biological drugs. The BPCIA (Biologics Price Competition and Innovation Act) provides that FDA may not approve a biosimilar application until 12 years after the date on which the reference product was first licensed.

In the EU, regulatory exclusivity is available in two forms: data exclusivity and marketing exclusivity. Generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity). This eight-year period is followed by a two-year period during which generics cannot be marketed (marketing exclusivity). The marketing exclusivity period can be extended to three years if, during the first eight-year period, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are deemed to provide a significant clinical benefit over existing therapies. This is known as the "8+2+1" rule.

In Japan, the regulatory exclusivity period varies: four years for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions; six years for new drugs containing a medicinal composition or requiring a new route of administration; eight years for drugs containing a new chemical entity; and ten years for orphan drugs or new drugs requiring pharmaco-epidemiological study.

Emerging markets

One of the main limitations on our operations in emerging market countries is the lack of effective intellectual property protection or enforcement for our products, which frequently do not provide non-patent exclusivity for innovative products. While the situation has gradually improved, the lack of protection for intellectual property rights or the lack of robust enforcement poses difficulties in certain countries. Additionally, in recent years and especially during the pandemic, a number of countries have waived or threatened to waive intellectual property protection for specific products, for example through compulsory licensing of generics. See "Item 3. Key Information — D. Risk Factors — Risks Relating to Sanofi's Structure and Strategy — The globalization of our business exposes us to increased risks in specific areas".

Pediatric extension

In the US and the EU, under certain conditions, it is possible to extend a product's regulatory exclusivity for an additional period of time by providing data on pediatric studies.

In the US, under certain conditions of the Hatch-Waxman Act, it may result in the FDA extending regulatory exclusivity and patent life by six months, to the extent these protections have not already expired (the so-called "pediatric exclusivity").

In Europe, a regulation on pediatric medicines provides for pediatric research obligations with potential associated rewards including extension of supplementary patent protection and six-month regulatory exclusivity for pediatric marketing authorization (for off-patent medicinal products).

In Japan, there is no pediatric research extension of patent protection for patented medicinal products. However, regulatory exclusivity may be extended from eight to ten years.

Orphan drug exclusivity

Under certain conditions, orphan drug exclusivity may be granted in the US to drugs intended to treat rare diseases or conditions. Orphan drug exclusivities also exist in the EU and Japan.

Product overview

We summarize below the intellectual property coverage (in some cases through licenses) of our most significant marketed products in terms of sales, in our major markets. In the discussion of patents below, we focus on active ingredient patents (compound patents) and, in the case of NCEs, on any later filed patents listed as applicable in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") or in its foreign equivalents. For biologics, the Orange Book listing does not apply.

These patents or their foreign equivalents tend to be the most relevant in the event of an application by a competitor to produce a generic or a biosimilar version of one of our products (see "— Challenges to Patented Products" below). In some cases, products may also benefit from pending patent applications or from patents not eligible for Orange Book listing (in the case of NCEs for example, patents claiming industrial processes). In each case below, we specify whether the active ingredient is claimed by an unexpired patent. Where patent terms have been extended to compensate for US Patent and Trademark Office (USPTO) delays in patent prosecution (Patent Term Adjustment – PTA) or for other regulatory delays, the extended dates are indicated below. The US patent expirations presented below reflect USPTO dates, and also reflect six-month pediatric extensions when applicable. Where patent terms have expired we indicate such information and mention whether generics are on the market.

We do not provide later filed patent information relating to formulations already available as an unlicensed generic. References below to patent protection in Europe indicate the existence of relevant patents in most major markets in the EU. Specific situations may vary by country.

We additionally set out any regulatory exclusivity from which these products continue to benefit in the US, EU or Japan. Regulatory exclusivities presented below incorporate any pediatric extensions obtained. While EU regulatory exclusivity is intended to be applied throughout the EU, in some cases Member States have taken positions prejudicial to our exclusivity rights.

	United States	European Union	Japan
Aubagio® (teriflunomide)	Compound: expired	Compound: expired	Compound: expired
		Later filed patent: coverage ranging through September 2030	Later filed patent: coverage ranging through March 2024
		Regulatory exclusivity: August 2024	
Alprolix® (eftrenonacog alfa)	Use: March 2028 with PTA* and PTE*	Compound: May 2024 (May 2029 with SPC* in most EU countries)	Compound: February 2026 with PTE*
	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)
	Regulatory exclusivity: March 2026	Regulatory exclusivity: May 2028	Regulatory exclusivity: July 2022
Cerezyme® (imiglucerase)	Patent: expired	Patent: expired	Patent: expired
Dupixent® (dupilumab)	Compound: October 2027 (March 2031 with PTE*)	Compound: October 2029 (September 2032 with SPC*)	Compound: October 2029 (May 2034 with PTE*)
	Later filed patents: coverage ranging through August 2040 (pending)	Later filed patents: coverage ranging through May 2039 (pending)	Later filed patents: coverage ranging through May 2039 (pending)
	Regulatory exclusivity: March 2029	Regulatory exclusivity: September 2027	Regulatory exclusivity: January 2026
Eloctate® (efmoroctocog alfa)	Compound: June 2028 with PTA* and PTE*	Use: May 2024 (November 2029 with SPC* in most EU countries)	Compound : August 2026 with PTE*
	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)
	Regulatory exclusivity: June 2026	Regulatory exclusivity: November 2025	Regulatory exclusivity: December 2022
Fabrazyme® (agalsidase beta)	Patent: expired	Patent: expired	Patent: expired Generics/biosimilars on the market
	Regulatory exclusivity: March 2028 pediatric indication (ages 2-8 with confirmed Fabry disease)		
Jevtana® (cabazitaxel)	Compound:	Compound: expired	Compound: expired
	Expired later filed patents: coverage ranging through October 2030	Later filed patents: coverage ranging through May 2036 (pending)	Later filed patents: coverage ranging through November 2030
	NCE Regulatory exclusivity: December 2023	Regulatory exclusivity: expired	Regulatory exclusivity: July 2022
Lantus® (insulin glargine)	Compound: expired	Compound: expired	Compound: expired
	Later filed patents ranging through April 2033	Later filed patent: June 2023	Later filed patent: June 2023
	Generics/biosimilars on the market	Generics/biosimilars on the market	Generics/biosimilars on the market
Lovenox® (enoxaparin sodium)	Compound: expired	Compound: expired	Compound: expired
	Generics/biosimilars on the market	Generics/biosimilars on the market	
Lumizyme®/Myozyme® (alglucosidase alfa)	Compound: expired	Compound: expired	Compound: expired
Plavix® (clopidogrel bisulfate)	Compound: expired	Compound: expired	Compound: expired
	Generics on the market	Generics on the market	Generics on the market
Toujeo® (insulin glargine)	Compound: expired	Compound: expired	Compound: expired
	Later filed patents: coverage ranging through May 2031	Later filed patents: coverage ranging through May 2031	Later filed patents: coverage ranging through July 2033 with PTE*

* *PTE: Patent Term Extension. – SPC: Supplementary Protection Certificate. – PTA: Patent Term Adjustment.*

Patents held or licensed by Sanofi do not in all cases provide effective protection against a competitor's generic version of our products. For example, notwithstanding the presence of unexpired patents, competitors launched generic versions of Allegra® in the US (prior to the product being switched to over-the-counter status) and Plavix® in the EU.

We caution the reader that there can be no assurance that we will prevail when we assert a patent in litigation and that there may be instances in which Sanofi determines that it does not have a sufficient basis to assert one or more of the patents mentioned in this report, for example in cases where a competitor proposes a formulation not appearing to fall within the claims of our formulation patent; a salt or crystalline form not claimed by our composition of matter patent; or an indication not covered by our method of use patent. See "Item 3. Key Information — D. Risk Factors — Risks Relating to Legal and Regulatory Matters — We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected".

As disclosed in Item 8. of this annual report, we are involved in significant litigation concerning the patent protection of a number of our products.

Challenges to patented products

— Abbreviated New Drug Applications (ANDAs)

In the US, generic companies have filed Abbreviated New Drug Applications (ANDAs) containing challenges to patents related to a number of our small molecule products. An ANDA is an application by a drug manufacturer to receive authority to market a generic version of another company's approved product, by demonstrating that the purportedly generic version has the same properties (safety and other technical data) as the original approved product. As a result of regulatory protection of our safety and other technical data, ANDA applications are generally four years after FDA approval, and include a challenge to a patent listed in the FDA's Orange Book. If the patent holder or licensee brings suit in response to the patent challenge within the statutory window, the FDA is barred from granting final approval to an ANDA during the 30 months following the expiry of the 5-year regulatory exclusivity (this bar is referred to in our industry as a "30-month stay") unless, before the end of the 30 months, the parties reach settlement or a court decision has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable.

FDA approval of an ANDA after this 30-month period does not resolve outstanding patent disputes, but it does remove the regulatory impediments to a product launch by a generic manufacturer willing to take the risk of later being ordered to pay damages to the patent holder.

Accelerated ANDA-type procedures are potentially applicable to many, but not all, of the products we manufacture. See "— B.6.3. Regulatory Framework — 6.3.2. Biosimilars" and "- Regulation" above. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against a competing product is not necessarily predictive of the future success or failure in the assertion of the same patent. See "Item 3. Key Information — D. Risk Factors — Risks Relating to Legal and Regulatory Matters — We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected".

— Section 505(b)(2) New Drug Applications in the US

Our products and patents are also subject to challenge by competitors via another abbreviated approval pathway, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. This pathway allows for approval for a wide range of products, especially for those products that represent only a limited change from an existing approved drug. The 505(b)(2) pathway is distinct from the ANDA pathway, which allows for approval of a generic product based on a showing that it is equivalent to a previously approved product.

Similarly, entities wishing to market a generic biologic can utilize an abbreviated approval pathway established in the PHS Act. This §351(k) pathway enables an applicant to rely on a reference product sponsor's data when seeking approval of a biological product shown to be biosimilar (highly similar with no clinically meaningful differences) or interchangeable with an FDA-licensed reference BLA product.

In the EU, a generic drug manufacturer may only reference the data of the regulatory file for the original approved product after data exclusivity has expired. However, there is no patent listing system in Europe comparable to the Orange Book, which would allow the patent holder to prevent the competent authorities from granting marketing authorization by bringing patent infringement litigation prior to approval. As a result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder's rights. Nevertheless, in most of these jurisdictions once the competing product is launched, and in some jurisdictions even prior to launch (once launch is imminent), the patent holder may seek an injunction against such marketing if it believes its patents are infringed. See Item 8. of this annual report.

B.7.2. Trademarks – Domain names – Copyright

Our products are sold around the world under trademarks that we consider to be of material importance in the aggregate. Our trademarks help to identify our products and to protect the sustainability of our growth. We generate new assets (trademarks, domain names, service marks) when creating global brands for new, innovative products. We support the development of the product, from the branding of biotech platforms to the protection of service marks for patient support programs.

Trademarks are particularly important to the commercial success of our products and services in a competitive marketplace, providing a strong visibility and assuring patients of the origin of the products.

Domain names are essential to inform a range of communities about what we do. We also pay close attention to ensuring that no damage is done to our reputation online.

We aim to ensure that the product trademarks we submit to healthcare authorities to obtain marketing authorizations are available, and are protected. In certain cases, we may enter into a coexistence agreement with a third party that owns potentially conflicting rights in order to avoid any risk of confusion and to secure our rights.

Ongoing digitization emphasizes the importance of securing copyright protection for software and web layouts.

We monitor and defend our trademarks based on a specific policy designed to prevent counterfeiting, trademark infringement and/or unfair competition.

B.8. Production and raw materials

We have opted to manufacture the majority of our products in-house. There are three principal stages in our production process: the manufacture of active ingredients, the transformation of those ingredients into drug products or vaccines, and the final packaging.

Our general policy is to produce our key active ingredients and main drug products at our own plants in order to reduce our dependence on external suppliers. We also rely on third parties for the manufacture and supply of specific active ingredients, drug products and medical devices. Active ingredients are manufactured using raw materials sourced from suppliers who have been subject to rigorous selection and approval procedures, in accordance with international standards and our own internal directives. We have outsourced some of our production under supply contracts associated with acquisitions of products or businesses or with Sanofi plant divestitures, or to

establish a local presence to capitalize on growth in emerging markets. Our pharmaceutical subcontractors follow our general quality and logistics policies, as well as meeting other criteria. See "Item 3. Key Information — D. Risk Factors — Risks Relating to Our Business".

We also obtain active ingredients from third parties under collaboration agreements. This applies in particular to the monoclonal antibodies developed with Regeneron.

Our production sites are divided into three categories:

- global sites, which serve all markets: located mainly in Europe, these facilities are dedicated to the manufacture of our active ingredients, injectable products, and a number of our main solid-form products;
- regional sites, which serve markets at regional level, giving us a strong industrial presence in emerging markets; and
- local sites, which serve their domestic market only.

Sanofi Pasteur produces vaccines at various sites, with the main locations situated in France, the United States, Canada, India, Mexico and China. The pharmaceutical site at Le Trait (France) also contributes to Sanofi Pasteur's industrial operations by making its sterile filling facilities available for vaccine manufacturing.

All of our production facilities are good manufacturing practice (GMP) compliant, in line with international regulations.

Our main sites are approved by the US FDA:

- the Specialty Care facilities in the United States (Framingham MA and Northborough MA), France (Lyon Gerland, Vitry-sur-Seine, Le Trait), Germany (Frankfurt), Ireland (Waterford) and Belgium (Geel);
- the General Medicines facilities in Germany (Frankfurt), France (Aramon, Sisteron, Ambarès and Tours), Italy (Anagni and Scoppito), Singapore (Jurong) and the United States (Ridgefield NJ);
- the chemical facilities producing active ingredients for third parties, including those located in France (Vertolaye, Saint-Aubin-les-Elbeuf), Germany (Frankfurt) and Hungary (Ujpest);
- the Consumer Healthcare facilities in France (Compiègne) and the United States (Chattanooga TN); and
- the Vaccines facilities in France (Marcy l'Étoile, Le Trait, Val-de-Reuil and Neuville-sur-Saône), the United States (Swiftwater PA) and Canada (Toronto).

Wherever possible, we seek to have multiple plants approved for the production of key active ingredients and our strategic finished products (this is the case with Lovenox® and Dupixent®, for example).

In May 2010, Genzyme's Allston facility in the United States entered into a consent decree with the US government. In March 2021, the Allston facility was divested; based on contractual obligations, the purchaser has assumed responsibility for fulfilling Genzyme's obligations under the consent decree.

More details about our manufacturing sites are given below at section "D. Property, Plant and Equipment".

B.9. Insurance and risk coverage

We are protected by five main insurance programs, relying not only on the traditional corporate insurance and reinsurance market but also on our direct insurance company, Carraig Insurance DAC (Carraig).

These five key programs cover Property & Business Interruption; General & Product Liability; Stock & Transit; loss and liability arising from cyber and digital risks; and Directors & Officers Liability.

Carraig participates in our coverage for various lines of insurance including Property, Stock & Transit, Cyber/Digital, and General & Product Liability. Carraig is run under the supervision of the Irish and European regulatory authorities, is wholly owned by Sanofi, and has sufficient resources to meet those portions of our risks that it has agreed to cover.

Carraig sets premiums for our entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company's reserves are regularly verified and confirmed by independent actuaries.

Our Property & Business Interruption program covers all our entities worldwide, in all territories where it is possible to use a centralized program operated by Carraig. By sharing risk between our entities, this approach enables us to set deductibles and cover appropriate to the needs of local entities before the market attachment point. It also incorporates a prevention program, including a comprehensive site visit schedule covering our production, storage, research and distribution facilities and standardized repair and maintenance procedures across all sites.

The Stock & Transit program protects all goods owned by Sanofi while they are in transit nationally or internationally whatever the means of transport, and all our inventories wherever they are located. Sharing risk between our entities through Carraig means that we can set deductibles at appropriate levels, for instance differentiating between goods that require temperature controlled distribution and those that do not. We have developed a prevention program with assistance from experts, implementing best practices in this area at our distribution sites.

Our Cyber/Digital insurance program protects our operations against loss originating from various sources, and against liability in respect of data security. Centralized through Carraig, the program enables us to set deductibles and cover appropriate to the needs of local entities before the market attachment point.

Our General & Product Liability program was renewed in 2021 for all our subsidiaries worldwide in all territories where it was possible to do so, despite reluctance in the insurance and reinsurance market to cover product liability risks for large pharma-biotech groups. For several years, insurers have been reducing product liability cover because of the difficulty of transferring risk for some products that have been subject to numerous claims.

The principal risk exposure for our pharmaceutical products is covered with low deductibles at country level, with a greater proportion of risk being retained. The level of risk self-insured by Sanofi (including via Carraig) before the market attachment point enables us to retain control over the management and prevention of risk. Our negotiations with third-party insurers and reinsurers are tailored to our specific risks. In particular, they allow for differential treatment of products in the development phase; for discrepancies in risk exposure between European countries and the United States; and for specific issues arising in certain jurisdictions, such as generics or biosimilar coverage in the United States. Coverage is adjusted every year to take account of the relative weight of new product liability risks such as those arising out of biotechnologies and new technology platforms.

Our cover for risks that are not specific to the pharma-biotech industry (general liability) is designed to address the potential impacts of our operations.

For all the insurance programs handled by Carraig, outstanding claims are covered by provisions for the estimated cost of settling all claims incurred but not paid at the balance sheet date, whether reported or not, together with all related claims handling expenses. Where there is sufficient data history from Sanofi or from the market for claims made and settled, management – with assistance from independent actuaries – prepares an actuarial estimate of our exposure to unreported claims for the risks covered. The actuaries perform an actuarial valuation of the company's IBNR (Incurred But Not Reported) and ALAE (Allocated Loss Adjustment Expense) liabilities at year end. Two ultimate loss projections (based upon reported losses and paid losses, respectively) are computed each year using various actuarial methods including the Bornhuetter-Ferguson method; those projections form the basis for the provisions set.

The Directors & Officers Liability program protects all legal entities under our control, and their directors and officers. Carraig is not involved in this program.

We also operate other insurance programs, but these are of much lesser importance than those described above.

All our insurance programs are backed by best in class insurers and reinsurers and are designed in such a way that we can integrate most newly acquired businesses without interruption of cover. Our cover has been designed to reflect our risk profile and the capacity available in the insurance market. By centralizing our major programs, we are able to provide world-class protection while limiting the premium increase in a global market with severe upward price pressure over the last three years.

B.10. Health, Safety and Environment

Our manufacturing and research operations are subject to increasingly stringent health, safety and environmental (HSE) laws and regulations. These laws and regulations are complex and rapidly changing, and Sanofi invests the necessary sums in order to comply with them. This investment, which aims to respect health, safety and the environment, varies from year to year.

Applicable environmental laws and regulations may require us to eliminate or reduce the effects of chemical substance discharge at our various sites. The sites in question may belong to Sanofi, and may be currently operational, or may have been owned or operational in the past. In this regard, Sanofi may be held liable for the costs of removal or remediation of hazardous substances on, under or in the sites concerned, or on sites where waste from activities has been stored, without regard to whether the owner or operator knew of or under certain circumstances caused the presence of the contaminants, or at the time site operations occurred the discharge of those substances was authorized.

As is the case for a number of companies in the pharmaceutical, chemical and intense agrochemical industries, soil and groundwater contamination has occurred at some of our sites in the past, and may still occur or be discovered at others. In Sanofi's case, such sites are mainly located in the United States, Germany, France, Hungary, Italy and the United Kingdom. As part of a program of environmental surveys conducted over the last few years, detailed assessments of the risk of soil and groundwater contamination have been carried out at current and former Sanofi sites. In cooperation with national and local authorities, Sanofi regularly assesses the rehabilitation work required and carries out such work when appropriate. Long-term rehabilitation work is in progress or planned in Mount Pleasant, Portland in the United States; Frankfurt in Germany; Brindisi in Italy; Dagenham in the United Kingdom; Ujpest in Hungary; Beaucaire, Valernes, Limay, Neuville and Vitry in France; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by Sanofi.

We may also have potential liability for investigation and cleanup at several other sites. We have established provisions for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. In France specifically, we have provided the financial guarantees for environmental protection required under French regulations.

Potential environmental contingencies arising from certain business divestitures are described in Note D.22.d. to the consolidated financial statements. In 2021, Sanofi spent €49 million on rehabilitating sites previously contaminated by soil or groundwater pollution.

Due to changes in environmental regulations governing site remediation, our provisions for remediation obligations may not be adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques involved, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations arising from the past involvement of Aventis in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision. See "Item 3.D. Risk Factors — Environmental Risks of Our Industrial Activities".

We have established, in accordance with our current knowledge and projections, provisions for cases already identified and to cover contractual guarantees for environmental liabilities relating to sites that have been divested. In accordance with Sanofi standards, a comprehensive review is carried out once a year on the legacy of environmental pollution. In light of data collected during this review, we adjusted our provisions to €650 million as of December 31, 2021 versus €713 million as of December 31, 2020. The terms of certain business divestitures, and the environmental obligations and retained environmental liabilities relating thereto, are described in Note D.22. to our consolidated financial statements.

To our knowledge, Sanofi did not incur any liability in 2021 for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial

compliance with current HSE laws and regulations and that all the environmental permits required to operate our facilities have been obtained.

Regular HSE audits are carried out by Sanofi in order to assess compliance with standards (which implies compliance with regulations) and to initiate corrective measures (50 internal audits performed in 2021). Moreover, more than 100 specific visits were performed jointly with experts representing our insurers.

Sanofi has implemented a worldwide master policy on health, safety and environment to promote the health and well-being of the employees and contractors working on its sites and respect for the environment. We consider this master policy to be an integral part of our commitment to social responsibility. In order to implement this master policy, Sanofi key requirements have been drawn up in the key fields of HSE management, HSE leadership, safety in the workplace, process safety, occupational hygiene, health in the workplace and protection of the environment.However, despite these efforts, Sanofi may be unsuccessful in the implementation of its policy to reduce and mitigate the harmful effects of its activities on the health and safety of its employees, customers or the general public and on the environment more generally. See “Item 3.B. Risk Factors” for further information.

Health

From the development of compounds to the commercial launch of new drugs, Sanofi research scientists continuously assess the effect of products on human health. This expertise is made available to employees through two committees responsible for chemical and biological risk assessment. Sanofi’s COVALIS *(Comité des Valeurs Limites Internes Sanofi)* Committee is responsible for the hazard determination and classification of all active pharmaceutical ingredients and synthesis intermediates handled at Sanofi facilities. This covers all active ingredients handled in production at company sites or in processes sub-contracted for manufacture. Any important issues involving raw materials or other substances that lack established occupational exposure limits may also be reviewed. The COVALIS Committee determines the occupational exposure limits required within Sanofi. Our TRIBIO Committee is responsible for classifying all biological agents according to their degree of pathogenicity, and applies rules for their containment and the preventive measures to be respected throughout Sanofi. See “Item 3. Key Information — D. Risk Factors — Environmental Risks of Our Industrial Activities — Risks from the handling of hazardous materials could adversely affect our results of operations”.

Appropriate occupational hygiene practices and programs are defined and implemented in each site. These practices consist essentially of containment measures for collective and individual protection against exposure in all workplaces where chemical substances or biological agents are handled. All personnel are monitored with an appropriate medical surveillance program, based on the results of professional risk evaluations linked to their duties.

In addition, dedicated resources have been created to implement the EU Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). To fully comply with the new European Regulation on Classification, Labeling and Packaging of chemicals, Sanofi has registered the relevant hazardous chemical substances with the European Chemicals Agency (ECHA).

Safety

Sanofi has rigorous policies to identify and evaluate safety risks and to develop preventive safety measures, and methods for checking their efficacy. Additionally, Sanofi invests in training that is designed to instill in all employees a sense of concern for safety, regardless of their duties. These policies are implemented on a worldwide scale to ensure the safety of all employees and to protect their health. Each project, whether in research, development or manufacturing, is subject to evaluation procedures, incorporating the chemical substance and process data communicated by the COVALIS and TRIBIO Committees described above. The preventive measures are designed primarily to reduce the number and seriousness of work accidents and to minimize exposures involving permanent and temporary Sanofi employees as well as our sub-contractors.

The French chemical manufacturing sites in Aramon, Sisteron and Vertolaye, as well as the plants located in the Hoechst Industry Park in Frankfurt, Germany, and the chemical production site in Budapest, Hungary, are listed Seveso III (from the name of the European directive that deals with potentially dangerous sites through a list of activities and substances associated with classification thresholds). In accordance with French law on technological risk prevention, the French sites are also subject to heightened security inspections due to the toxic or flammable materials stored on the sites and used in the operating processes.

Risk assessments of processes and installations are drawn up according to standards and internal guidelines incorporating the best state of the art benchmarks for the industry. These assessments are used to fulfill regulatory requirements and are regularly updated. Particular attention is paid to any risk-generating changes such as process or installation changes, as well as changes in production scale and transfers between industrial or research units.

We have specialized process safety-testing laboratories that are fully integrated into our chemical development activities, apply methods to obtain the physico-chemical parameters of manufactured chemical substances (intermediate chemical compounds and active ingredients) and apply models to measure the effect of potentially leachable substances in the event of a major accident. In these laboratories the parameters for qualifying hazardous reactions are also determined, in order to define scale-up process conditions while transferring from development stage to industrial scale. We use these data to enhance the relevance of our risk assessments.

We believe that the safety management systems implemented at each site, the hazard studies carried out and the risk management methods implemented, as well as our third-party property insurance policies covering any third-party physical damage, are consistent with legal requirements and the best practices in the industry, although no guarantee can be given that they will prevent accidents of various kinds.

Environment

We have committed to an ambitious policy aimed at limiting the direct and indirect impacts of our activities on the environment, throughout the life cycle of our products. We have identified five major environmental challenges relating to our businesses: greenhouse gas emissions and climate disruption; water; pharmaceuticals in the environment; waste; and biodiversity.

The initiatives already implemented since 2010 are continuing, and we have been keen to give them fresh impetus through the Planet Mobilization program. Reflecting our environment strategy out to 2030, the program sets more ambitious targets for reducing

environmental impacts across the entire value chain. Planet Mobilization is a global project that involves all of the Company's resources in defining objectives and engaging with external partners.

Compared with 2019 figures, we are undertaking to reduce our carbon emissions by 55% by the end of 2030 and reach carbon-neutral status by 2030 on our scope 1, 2 & 3 (direct and indirect emissions for all activities). We have also set ourselves the target of achieving sustainable water resource management, especially at sites which are under hydric stress. On this new scope, by the end of 2021, we had reduced CO_2 emissions by 25% (scope 1 and 2) and water consumption by 11%.

Overall waste recycling at sites is already above 73% and is expected to be more than 90% by the end of 2025. The discharge rate had dropped to 7% at the end of 2021 and we have committed to move towards a maximum of 1% by 2025. Biodiversity management at our sites is also a priority, with the aim of making all employees aware of this challenge and implementing risk assessment and management plans at priority sites.

Finally, we are pursuing the policy we began in 2010 of managing pharmaceutical products in the environment throughout their life cycles. At the end of 2021, all priority production sites have a life cycle management plan.

In line with this approach, we have committed to the "Roadmap AMR 2020" initiative, which aims to combat microbial resistance to antibiotics. The initiative brings together thirteen of the major players in the pharmaceutical industry, and will involve co-producing reference guides and methodologies for sustainable management of antibiotics in the pharmaceutical sector. The initiative includes a specific commitment with respect to antibiotic production sites that are operated by signatories or their suppliers, involving firstly the definition and deployment of a shared framework for managing potential waste, and secondly the establishment of environmental thresholds. See "Cautionary statement regarding forward-looking statements" and "Item 3.D. Risk Factors".

C. Organizational Structure

C.1. Significant Subsidiaries

Sanofi is the holding company of a consolidated group consisting of almost 290 companies. The table below sets forth our significant subsidiaries as of December 31, 2021. For a fuller list of the principal companies in our consolidated group, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

Significant subsidiary	Date of incorporation	Country of incorporation	Principal activity	Financial and voting interest
Aventis Inc.	July 1, 1968	United States	Pharmaceuticals	100%
Genzyme Corporation	November 21, 1991	United States	Pharmaceuticals	100%
Genzyme Europe B.V.	October 24, 1991	Netherlands	Pharmaceuticals	100%
Hoechst GmbH	July 8, 1974	Germany	Pharmaceuticals	100%
Sanofi-Aventis Deutschland GmbH	June 30, 1997	Germany	Pharmaceuticals	100%
Sanofi-Aventis Participations SAS	February 25, 2002	France	Pharmaceuticals	100%
Sanofi-Aventis Singapore Pte Ltd	May 14, 1997	Singapore	Pharmaceuticals	100%
Sanofi Biotechnology	December 23, 2013	France	Pharmaceuticals	100%
Sanofi Foreign Participations B.V.	April 29, 1998	Netherlands	Pharmaceuticals	100%
Sanofi Winthrop Industrie	December 11, 1972	France	Pharmaceuticals	100%
Sanofi Pasteur Inc.	January 18, 1977	United States	Pharmaceuticals	100 %

Since 2009, we have transformed Sanofi through numerous acquisitions (see "A. History and Development of the Company" above), in particular those of Genzyme in April 2011, Boehringer Ingelheim (BI) Consumer Healthcare in January 2017, Bioverativ in March 2018, Ablynx in June 2018, Synthorx in January 2020, Principia in September 2020, Translate Bio in September 2021 and Kymab in April 2021. The financial effects of the Genzyme acquisition are presented in Note D.1.3. to our consolidated financial statements for the year ended December 31, 2013, included in our annual report on Form 20-F for that year. At the end of December 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) ended their Sanofi Pasteur MSD joint venture. The financial effects of the resulting divestment/acquisition are presented in Note D.1.2. to our consolidated financial statements for the year ended December 31, 2016, included in our annual report on Form 20-F for that year. On January 1, 2017, Sanofi and Boehringer Ingelheim (BI) finalized the strategic transaction agreed in June 2016, involving the exchange of Sanofi's Animal Health business (Merial) for BI's Consumer Healthcare business. The financial effects of this transaction are presented in Note D.1. to our consolidated financial statements for the year ended December 31, 2017, included in our annual report on Form 20-F for that year. The financial effects of the Bioverativ and Ablynx acquisitions are presented in Note D.1.1. to our consolidated financial statements for the year ended December 31, 2018, included in our annual report on Form 20-F for that year. The financial effects in 2020 of the Synthorx and Principia acquisitions, and the financial effects in 2021 of the Kymab, Kiadis, Tidal, Translate Bio, Kadmon and Origimm acquisitions, are presented in Notes D.1 and D.2. to our consolidated financial statements for the year ended December 31, 2021, included in the annual report on Form 20-F for that year.

In certain countries, we carry on some of our business operations through joint ventures with local partners. In addition, we have entered into worldwide collaboration agreements with Regeneron relating to Zaltrap®, Praluent®, Dupixent®, Kevzara® and Libtayo®. For further information, refer to Note C. "Principal Alliances" to our consolidated financial statements.

C.2. Internal organization of activities

Sanofi and its subsidiaries collectively form a group organized around three activities: Pharmaceuticals (General Medicines and Specialty Care), Vaccines, and Consumer Healthcare.

Within Sanofi, responsibility for research and development (R&D) in their respective fields rests with Sanofi and Genzyme Corporation in Pharmaceuticals, and with Sanofi Pasteur and Sanofi Pasteur, Inc. in Vaccines. However, within our integrated R&D organization, strategic priorities are set and R&D efforts coordinated on a worldwide scale. In fulfilling their role in R&D, the aforementioned companies subcontract R&D to those of their subsidiaries that have the necessary resources. They also license patents, manufacturing know-how and trademarks to certain of their French and foreign subsidiaries. Those licensee subsidiaries manufacture, commercialize and distribute the majority of our products, either directly or via local distribution entities.

Our industrial property rights, patents and trademarks are mainly held by the following companies:

- pharmaceuticals: Sanofi, Sanofi Mature IP and Sanofi Biotechnology SAS (France), Sanofi-Aventis Deutschland GmbH (Germany), Ablynx (Belgium), Genzyme Corporation, Bioverativ Inc. ;
- vaccines: Sanofi Pasteur (France), Sanofi Pasteur, Inc. (US) and Translate Bio (US)

For a description of our principal items of property, plant and equipment, see "— D. Property, Plant and Equipment" below. Our property, plant and equipment is held mainly by the following companies:

- in France: Sanofi Pasteur SA, Sanofi Chimie, Sanofi Winthrop Industrie, and Sanofi-Aventis Recherche & Développement;
- in the United States: Sanofi Pasteur, Inc., Genzyme Therapeutics Products LP, Genzyme Corporation and Translate Bio;
- in Germany: Sanofi-Aventis Deutschland GmbH;
- in Canada: Sanofi Pasteur Limited;
- in Belgium: Genzyme Flanders BVBA; and
- in Ireland: Genzyme Ireland Limited.

C.3. Financing and financial relationships between group companies

The Sanofi parent company raises the bulk of the Company's external financing and uses the funds raised to meet, directly or indirectly, the financing needs of its subsidiaries. The parent company operates a cash pooling arrangement under which any surplus cash held by subsidiaries is managed centrally. There is also a centralized foreign exchange risk management system in place, whereby the parent company contracts hedges to meet the needs of its principal subsidiaries.

Consequently, at December 31, 2021, the Sanofi parent company held 98% of our external financing and 88% of our surplus cash.

Sanofi European Treasury Center SA (SETC), a 100%-owned Sanofi subsidiary incorporated in 2012 under the laws of Belgium, is dedicated to providing financing and various financial services to our subsidiaries.

D. Property, plant and equipment

D.1. Overview

Our headquarters are located in Paris, France. See "— D.4. Office Space" below.

We operate our business through office premises and research, production and logistics facilities in approximately 90 countries around the world. Our office premises house all of our support functions, plus operational representatives from our subsidiaries and the Company.

A breakdown of our sites by use and by ownership status (owned versus leasehold) is provided below. This breakdown is based on surface area. All surface area figures are unaudited.

Breakdown of sites by use	
Industrial	61%
Research	12%
Offices	14%
Logistics	9%
Other	4%

Breakdown of sites by ownership status	
Leasehold	25%
Owned	75%

D.2. Description of our sites

Sanofi industrial sites

As part of the process of transforming Sanofi and creating Global Business Units, we are continuing to adapt the organization of the Industrial Affairs department in support of our new business model.

The Industrial Affairs department focuses on customer needs and service quality; the sharing of "Sanofi Manufacturing System" good manufacturing practices; and the development of a common culture committed to quality.

In 2020, Industrial Affairs modified its organization to align on the new Global Business Units structure comprising Specialty Care, General Medicines, Vaccines and Consumer Health Care.

In February 2020, we announced a plan to create a major leading European company dedicated to the production and marketing of active pharmaceutical ingredients (API) to third parties as well as to Sanofi. This involves creating a standalone company combining our API commercial and development activities with six of our European API production sites: Brindisi (Italy), Frankfurt Chemistry (Germany), Haverhill (UK), Saint-Aubin-les-Elbeuf (France), Újpest (Hungary), and Vertolaye (France). This plan is proceeding as announced, with the carve-out to EUROAPI (a Sanofi subsidiary) of the relevent activities having been completed by the end of December 2021. An IPO on Euronext Paris is envisaged in the first half of 2022, subject to market conditions and obtaining required market authority approvals.

The Industrial Affairs department is also responsible for Sanofi Global HSE and Global Supply Chain.

At the end of 2021, we were carrying out industrial production at 67 sites in 31 countries:

- 8 sites for our Specialty Care operations;
- 30 sites for our General Medicines operations;
- 6 sites for our Third-Party API operations;
- 12 sites for our Consumer Healthcare operations; and
- 11 sites for the industrial operations of Sanofi Pasteur in vaccines.

The quantity of units sold in 2021, including in-house and outsourced production, was 4.8 billion, comprising:

- Pharmaceuticals: 2.8 billion units;
- Consumer Healthcare: 1.8 billion units; and
- Vaccines: 180 million boxes.

We believe that our production facilities are in compliance with all material regulatory requirements, are properly maintained and are generally suitable for future needs. We regularly inspect and evaluate those facilities with regard to environmental, health, safety and security matters, quality compliance and capacity utilization. For more information about our property, plant and equipment, see Note D.3. to our consolidated financial statements, included at Item 18. of this annual report, and section “B.8. Production and Raw Materials” above.

Our main production sites by volume are:

- Le Trait (France), Frankfurt (Germany), Waterford (Ireland), Geel (Belgium) and Framingham (United States) for Specialty Care;
- Aramon, Sisteron and Ambarès (France), Frankfurt (Germany), Csanyikvölgy (Hungary), Lüleburgaz (Turkey), Campinas (Brazil), Jurong (Singapore) and Hangzhou (China) for General Medicines products;
- Compiègne and Lisieux (France), Cologne (Germany), Origgio (Italy), Chattanooga (United States) and Ocoyoacac (Mexico) for Consumer Healthcare products; and
- Marcy-l’Étoile and Val-de-Reuil (France), Toronto (Canada), Swiftwater (United States) and Hyderabad (India) for vaccines.

Research & Development sites

In Pharmaceuticals, research and development activities are conducted at the following sites:

- four operational sites in France: Chilly-Mazarin/Longjumeau, Montpellier, Strasbourg and Vitry-sur-Seine/Alfortville;
- three sites in the rest of Europe (Germany, Belgium and the Netherlands), the largest of which is in Frankfurt (Germany);
- six sites in the United States: Bridgewater, Cambridge, Framingham/Waltham, Great Valley, San Francisco and San Diego; and
- in Asia, three sites in China (Beijing, Shanghai and Chengdu).

Vaccines research and development sites are:

- Swiftwater, Cambridge and Orlando (United States);
- Marcy-l’Étoile/Lyon (France); and
- Toronto (Canada).

D.3. Acquisitions, capital expenditures and divestitures

The carrying amount of our property, plant and equipment at December 31, 2021 was €10,028 million. During 2021, we invested €1,504 million (see Note D.3. to our consolidated financial statements, included at Item 18. of this annual report), mainly in increasing capacity and improving productivity at our various production and R&D sites.

Our principal acquisitions, capital expenditures and divestitures in 2019, 2020 and 2021 are described in Notes D.1. & D.2. (“Changes in the scope of consolidation”), D.3. (“Property, plant and equipment”) and D.4. (“Goodwill and other intangible assets”) to our consolidated financial statements, included at Item 18. of this annual report.

As of December 31, 2021, our firm commitments in respect of future capital expenditures amounted to €769 million. The principal locations involved were: for the Pharmaceuticals segment, the industrial facilities at Frankfurt (Germany); Le Trait, Maisons-Alfort, Compiègne, and Ambares (France); Cambridge (United States); Geel (Belgium); Origgio, Anagni, Brindisi, and Scoppito (Italy); and for the Vaccines segment, the facilities at Swiftwater (United States), Toronto (Canada), Marcy-l’Étoile, Neuville-sur-Saône and Val-de-Reuil (France), and Singapore.

In the medium term and assuming no changes in the scope of consolidation, we expect to invest on average some €1.4 billion a year in property, plant and equipment. We believe that our own cash resources and the undrawn portion of our existing credit facilities will be sufficient to fund these expenditures.

Our principal ongoing capital expenditures are described below.

Speciality care

Our Specialty Care industrial operations are organized around two end-to-end clusters. We have four dedicated biotechnology hubs: Paris/Lyon (France), Frankfurt (Germany), Geel (Belgium) and Boston Area (United States). The Bioatrium project, a joint venture between Sanofi and Lonza (Switzerland) set up in 2017 to increase bioproduction capacity, is proceeding on schedule. Exploiting the innovative techniques on which biotech relies, including cell and microbiological culture and the development of viral vectors, calls for highly specific knowledge and expertise backed by dedicated production platforms to support global product launches.

The Waterford and Le Trait sites manufacture pre-filled Dupixent® syringes.

General medicines

Our General Medicines industrial operations are organized through end-to-end clusters, with chemistry, pharmaceutical and injectable sites organized through a network of over 31 regional and local industrial sites in 20 countries, supporting growth in those markets.

This new organization encompasses a dedicated Launch Sites cluster from API manufacturing to finished goods packaging (Sisteron, Aramon, Ambarès, Scoppito).

The Frankfurt facility is our principal site for the manufacture of diabetes treatments.

Consumer healthcare

The pharmaceutical industrial operations of our Consumer Healthcare (CHC) business are spread across a dedicated network. Global markets are supplied from our facilities at Compiègne (France) and Cologne (Germany). We have recently invested in projects to bring various manufacturing operations related to our acquisition of Boehringer Ingelheim's CHC business in-house, mainly to our sites at Compiègne (France) and Suzano (Brazil).

Vaccines (Sanofi Pasteur)

Sanofi Pasteur's industrial operations are in a major investment phase, preparing for the upcoming growth of our influenza and Polio/Pertussis/Hib franchises, plus the mid-term growth linked to our New Vaccines pipeline. Major investments were announced in 2020 and 2021 with a new Evolutive Facility in France (Neuville-Sur-Saone) and a new facility in Singapore for our New Vaccines pipeline. Other major investments are under way in France (including construction of a new influenza vaccine building at Val-de-Reuil), Canada (a new pertussis vaccine building), the US and Mexico.

Innovation and culture of industrial excellence

The ambition of our Industrial Affairs department is to continue to raise quality standards in Sanofi's production activities, and to remain a world leader and a benchmark in the global pharmaceutical industry. To achieve this goal, all our activities share a common culture of industrial excellence, enshrined in the Sanofi Manufacturing System. This sets out a series of priorities (such as customer service, constant improvement, site network optimization and transverse optimization) that constitute our industrial vision and will be crucial to our mutual success.

In terms of operational excellence, we continue to build on our Top Decile performance program, focused on core sites and fully leveraging digital opportunities.

D.4. Office space

As part of the transformation of Sanofi, we are undertaking major real estate programs with two core objectives: to bring our teams together on single sites in new workspaces that favor agility, cross-fertilization and communication, and to rationalize office space while achieving a responsible environmental footprint.

This transformation of workspaces to flexible mode has already reached over 21,000 of our people around the globe, and provides strong support for our various operations to attain their objectives. The rollout covers all regions worldwide, and a number of projects are currently under way. These include projects in the Greater Paris region (relocation of our headquarters to *avenue de la Grande-Armée* in the seventeenth arrondissement of Paris, and closure of the Croix-de-Berny site at Antony), and further projects in Spain, Hungary and the United States. In 2021, we reviewed our use of office space throughout the world to increase efficiency in all markets, building on hybrid workspace initiatives and the impact of new workplace paradigm shifts arising out of the the COVID-19 pandemic. Finally, we continue to divest sites that are not core to our ongoing business model.

Item 4A. Unresolved Staff Comments

N/A

Item 5. Operating and Financial Review and Prospects

You should read the following discussion in conjunction with our consolidated financial statements and the notes thereto included in this annual report at Item 18.

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS endorsed by the European Union as of December 31, 2021.

The following discussion contains forward-looking statements that involve inherent risks and uncertainties. Actual results may differ materially from those contained in such forward-looking statements. See "Cautionary Statement Regarding Forward-Looking Statements" at the beginning of this document.

Unless otherwise stated, all financial variations in this item are given on a reported basis.

The discussion of our operating and financial review and prospects for the years ended December 31, 2020 and December 31, 2019, can be found in Part I, Item 5. of our Form 20-F filed on March 4, 2021, including a presentation of our consolidated income statements for the years ended December 31, 2020 and December 31, 2019 in "Item 5. — A.2. Results of operations" of our Form 20-F filed on March 4, 2021.

A. Operating results

A.1. Significant operating information

A.1.1. 2021 Overview

During 2021, Sanofi continued to implement its **"Play to Win"** strategy, involving major decisions and positive actions that will support and rebuild the competitive margins necessary for Sanofi to continue to deliver on its mission. The strategy is based on four major priorities: focus on growth, lead with innovation, accelerate efficiency, and reinvent how we work. For further information about our strategy, refer to "— Item 4. — B.1. Strategy". Other significant events of the year are described below.

On January 11, 2021, Sanofi and **Kymab**, a clinical-stage biopharmaceutical company developing fully human monoclonal antibodies with a focus on immune-mediated diseases and immuno-oncology therapeutics, announced that they had entered into an agreement under which Sanofi would acquire Kymab for an upfront payment of approximately $1.1 billion and up to $350 million contingent upon attainment of certain development milestones. On April 9, 2021, Sanofi announced that it had successfully completed this acquisition, thereby retaining full global rights to KY1005, a fully human monoclonal antibody that targets the key immune system regulator OX40L and has the potential to treat a wide variety of immune-mediated diseases and inflammatory disorders.

On January 12, 2021, Sanofi unveiled **EUROAPI** as the name of the future industry-leading European company dedicated to the development, production and marketing of active pharmaceutical ingredients (API). Sanofi also announced the appointment of Karl Rotthier as the Chief Executive Officer of EUROAPI effective January 18, 2021. An IPO on Euronext Paris is envisaged in the first half of 2022, subject to market conditions and obtaining required market authority approvals.

On February 12, 2021, Sanofi announced an all-cash offer to all holders of **Kiadis** shares, to acquire their shares at an offer price of €5.45 (cum dividend). Completion of the acquisition was announced on April 16, 2021. Kiadis is a clinical-stage biopharmaceutical company developing natural killer (NK) cell therapies for patients with potentially life-threatening diseases. NK cells seek and identify malignant cancer cells and have broad application across various tumor types. Kiadis's NK cell-based medicines will be developed alone and in combination with Sanofi's existing pipeline and platforms.

On March 31, 2021, Sanofi announced an investment of over €600 million to construct a **new vaccine manufacturing facility** at its existing site in Toronto, Canada. The new facility will provide additional antigen and filling capacity for Sanofi's Fluzone® High-Dose quadrivalent influenza vaccine, helping to increase supply availability in Canada, the United States and Europe. Sanofi expects this new facility to be operational in 2026, following design, construction, testing and qualification of the facility and equipment. Fluzone® High-Dose quadrivalent influenza vaccine is currently manufactured exclusively by Sanofi Pasteur, Sanofi's vaccines global business unit, at its Swiftwater, Pennsylvania site in the United States. Sanofi Pasteur has an ongoing investment program expanding its manufacturing capabilities for influenza vaccines. Two new facilities, in Swiftwater and in Val-de-Reuil (France), will start to operate in the coming years.

On April 7, 2021, Sanofi's Chief Executive Officer Paul Hudson outlined several key projects that the company will implement to increase the impact of its **Corporate Social Responsibility** (CSR) strategy. Embedded in Sanofi's long-term strategy, the company's commitment is based on four pillars in which Sanofi is well positioned to make a difference: access to medicines, support for vulnerable communities, preservation of the environment, and inclusion and diversity of its employees. See "Item 4.B. Information on the Company — Business Overview — Strategy".

On April 9, 2021, Sanofi acquired **Tidal Therapeutics**, a privately owned, pre-clinical stage biotech company with a novel mRNA-based approach for in vivo reprogramming of immune cells. The new technology platform will expand Sanofi's research capabilities in immuno-oncology and inflammatory diseases, and may have applicability to other disease areas as well. Sanofi acquired Tidal Therapeutics for an upfront payment of $160 million and up to $310 million contingent upon attainment of certain development milestones.

On April 12, 2021, Sanofi announced a €400 million investment over five years to create a one-of-a-kind **vaccine production center** in Singapore, pushing the boundaries of operations through cutting edge digital manufacturing technologies. In partnership with the Singapore Economic Development Board (EDB), the new site will mainly supply the Asian region and complement existing Sanofi manufacturing capacities in Europe and North America.

On May 6, 2021, Sanofi entered into a three-year research collaboration with **Stanford University School of Medicine**. Together, we will work to advance the understanding of immunology and inflammation through open scientific exchange. Additionally, Sanofi will provide funding and scientific inputs into projects of mutual interest, crossing multiple therapeutic areas including autoimmune diseases and inflammatory conditions.

On June 29, 2021, Sanofi announced that it will invest approximately €400 million annually in a first-of-its-kind **mRNA vaccines** Center of Excellence. The Center will work to accelerate the development and delivery of next-generation vaccines by bringing together approximately 400 dedicated employees and integrating end-to-end mRNA vaccine capabilities with dedicated R&D, digital, and Chemistry, Manufacturing and Controls (CMC) teams across sites at Cambridge, MA (US) and Marcy-l'Étoile, Lyon (France).

On July 13, 2021, Sanofi announced becoming a Premium Partner of Paris 2024 for the **Olympic and Paralympic Games being held in Paris in 2024**. For Sanofi, whose headquarters are based in Paris, this commitment to Paris 2024 is a unique opportunity to engage its 100,000 employees in one of the largest sporting events in the world. Sanofi's commitment to Paris 2024 also highlights the company's societal impact strategy and affirms its support of the values of inclusion, diversity and openness to the world. The company welcomes the objectives of Paris 2024 to foster the values of the Olympic and Paralympic Games to increase their accessibility to the public and make them more sustainable and Sanofi intends to contribute by highlighting the benefits of physical activity on health.

On August 3, 2021, as part of Sanofi's endeavor to accelerate the application of messenger RNA (mRNA) to develop therapeutics and vaccines, the company entered into a definitive agreement with **Translate Bio**, a clinical-stage mRNA therapeutics company, under which Sanofi will acquire all outstanding shares of Translate Bio for $38.00 per share in cash, which represents a total equity value of approximately $3.2 billion (on a fully diluted basis). The acquisition was finalized on September 14, 2021.

On September 8, 2021, Sanofi entered into a definitive merger agreement with **Kadmon** Holdings, Inc. a biopharmaceutical company that discovers, develops, and markets transformative therapies for disease areas of significant unmet medical needs. The acquisition supports Sanofi's strategy of continuing to grow its General Medicines core assets, and will immediately add Rezurock™ (belumosudil) to its transplant portfolio. Rezurock™ is a recently FDA-approved, first-in-class treatment for chronic graft-versus-host disease (cGVHD) for adult and pediatric patients 12 years and older who have failed at least two prior lines of systemic therapy. Shareholders of Kadmon common stock will receive $9.50 per share in cash, which represents a total equity value of approximately $1.9 billion (on a fully diluted basis). The acquisition of Kadmon by Sanofi was completed on November 9, 2021.

On September 28, 2021, Sanofi announced that despite positive interim results from Phase I/II trials of its **mRNA COVID-19 vaccine** candidate, the company had decided not to pursue development of that candidate. Sanofi will instead focus on completing the final development steps of its COVID-19 recombinant vaccine, developed in partnership with GSK.

On November 18, 2021, Sanofi announced an equity investment of €155 million in **Owkin**, along with a new strategic collaboration around discovery and development programs in four types of cancer involving an exclusivity fee up to €90 million spread over three years plus additional milestone-based payments. Owkin, an artificial intelligence (AI) and precision medicine company, builds best-in-class predictive biomedical AI models and robust data sets. With the ambition to optimize clinical trial design and detect predictive biomarkers for diseases and treatment outcomes, this collaboration will support Sanofi's growing oncology portfolio in three core areas: lung cancer, breast cancer and multiple myeloma. To intensify medical research with AI in a privacy-preserving way, Owkin has assembled a global research network powered by federated learning, which allows data scientists to securely connect to decentralized, multi-party data sets and train AI models without having to pool data. This approach will complement Sanofi's emerging strengths in oncology, as the company's scientists apply cutting-edge technology platforms to develop potentially life-transforming medicines for cancer patients worldwide.

On December 1, 2021, Sanofi entered into an agreement to acquire **Origimm Biotechnology GmbH**, a privately owned Austrian biotechnology company specializing in the discovery of virulent skin microbiome components and antigens from bacteria that cause skin disease, such as acne. This acquisition is a further step in executing Sanofi's global "Play to Win" strategy, seeking out growth opportunities, and building an industry-leading vaccines pipeline. The deal will add ORI-001 to Sanofi's early-stage pipeline. ORI-001 is a therapeutic acne vaccine candidate based on recombinant proteins, and entered preliminary clinical studies in the third quarter of 2021. In parallel, Sanofi is working to develop additional antigen versions and expects to leverage its next-generation mRNA platform in a Phase I/II trial to start in 2023. The acquisition closed in December 2021.

On December 21, 2021, Sanofi announced that it had entered into an agreement to acquire **Amunix Pharmaceuticals, Inc.**, an immuno-oncology company leveraging its proprietary, clinically validated XTEN® and its innovative universal protease-releasable masking technology platform (Pro-XTEN™), to discover and develop transformative T-cell engagers (TCE) and cytokine therapies for patients with cancer. Amunix's pipeline, which includes lead candidate AMX-818, a masked HER2-directed TCE, offers a strong strategic fit with Sanofi's focus on developing potentially transformative cancer therapies in immuno-oncology. Under the terms of the agreement, Sanofi will acquire Amunix for an upfront payment of approximately $1 billion and up to $225 million upon achievement of certain future development milestones. The acquisition was completed on February 8, 2022.

Highlights of Sanofi's research and development efforts in 2021 in the Pharmaceuticals segment included the launch of a Phase III trial (XTEND-Kids) evaluating **efanesoctocog alfa** (BIVV001) in pediatric hemophilia A patients, and of a second pivotal trial (AERIFY-2) evaluating **itepekimab** in chronic obstructive pulmonary disease (COPD). In the Vaccines segment, Sanofi and GSK announced the launch of their Phase III clinical study to assess the safety, efficacy, and immunogenicity of their adjuvanted recombinant-protein COVID-19 vaccine candidate. Positive booster data show that neutralizing antibodies increased across all primary vaccines received (mRNA or adenovirus) in a 9- to 43-fold range and for all age groups tested, with a good safety and tolerability profile. The Phase III trial is ongoing in order to generate the increased number of events needed for analysis, given that populations around the world are increasingly exposed to COVID-19 variants. On December 8, 2021, the New England Journal of Medicine (NEJM) published positive results from a pivotal clinical trial of **Dupixent®** (dupilumab) in children aged 6 to 11 years with uncontrolled moderate-to-severe asthma. Regulatory reviews are ongoing in the European Union. On December 13, 2021, Sanofi announced positive Phase III results showing that adding **Dupixent®** (dupilumab) to standard-of-care topical corticosteroids (TCS) significantly improved skin clearance and reduced overall disease severity and itch in infants and children aged 6 months to 5 years with uncontrolled moderate-to-severe atopic dermatitis. Data from two Phase III studies demonstrating that **fitusiran** significantly reduced bleeds in people with hemophilia A or B, with or without inhibitors, were presented at the American Society of Hematology (ASH) congress.

In 2021, Sanofi obtained regulatory marketing approval for a number of products. In the United States, the PD-1 inhibitor **Libtayo®** (cemiplimab-rwlc) received full approval for locally advanced basal cell carcinoma (BCC) and accelerated approval in metastatic BCC, following a priority review by the US Food and Drug Administration (FDA). Libtayo® is now approved for the two most common advanced skin cancers in the United States. The European Commission also approved Libtayo® for the treatment of metastatic or locally advanced BCC in adults. The FDA and the European Commission approved Libtayo® for the first-line treatment of patients with advanced non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression. The FDA and the European Commission approved **Sarclisa®** (isatuximab-irfc), in combination with carfilzomib and dexamethasone, for adult patients with relapsed and refractory multiple myeloma who have received one to three prior therapies. The European Commission approved **Aubagio®** (teriflunomide) for the treatment of pediatric patients aged 10 to 17 years with relapsing-remitting multiple sclerosis (MS). The approval confirms Aubagio® as the first oral therapy for first-line treatment of children and adolescents with MS in the European Union. The FDA approved **Nexviazyme®** (avalglucosidase alfa-ngpt) for the treatment of patients one year of age and older with late-onset Pompe disease, a progressive and debilitating muscle disorder that impairs a person's ability to move and breathe. The FDA also approved **Dupixent®** (dupilumab) as an add-on maintenance treatment of patients aged 6 to 11 years with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid-dependent asthma. In China, **Dupixent®** was approved for the treatment of atopic dermatitis in adolescents aged 12 to 17 years.

For further information about the pharmaceutical products and vaccines we sell, and about our research and development portfolio, refer to "— Item 4.B. — Business Overview".

Our net sales for 2021 amounted to €37,761 million, an increase of 4.8% from 2020. At constant exchange rates (CER[(1)]), net sales rose by 7.1%, due mainly to growth in sales for our Specialty Care global business unit (driven by a solid performance from Dupixent®), our Vaccines business, and our Consumer Healthcare global business unit. Those positive effects more than offset a decrease in sales for our General Medicines global business unit, in line with the streamlining of our non-core product portfolio and lower sales of Lantus® and Aprovel®.

Net income attributable to equity holders of Sanofi amounted to €6,223 million for 2021, compared with €12,294 million in 2020. This €6,071 million decrease mainly reflected the €7,382 million gain recognized in 2020 on the divestment of Regeneron shares following the transaction of May 29, 2020. Earnings per share was €4.97 in 2021, compared with €9.81 in 2020. Business net income[(2)] was €8,213 million, up 11.8% on 2020, while business earnings per share (business EPS[(2)]) was 11.9% higher than in 2020 at €6.56.

Our net debt[(3)] increased from €8,790 million as of December 31, 2020 to €9,983 million as of December 31, 2021, due in particular to cash outflows related to investing activities during the year, and more specifically to our acquisitions of Kadmon, Translate Bio and Kymab. At the Annual General Meeting on May 3, 2022, we will ask our shareholders to approve a dividend of €3.33 per share for the 2021 financial year, representing a payout of 50.8% of our Business net income.

A.1.2. Impacts of competition from generics and biosimilars

Some of our flagship products continued to suffer sales erosion in 2021 under the impact of competition from generics and biosimilars. We do not believe it is possible to state with certainty what level of net sales would have been achieved in the absence of generic competition. A comparison of our consolidated net sales for the years ended December 31, 2021 and 2020 (see "— A.2. Results of Operations — Year Ended December 31, 2021 Compared with Year Ended December 31, 2020" below) for the main products affected by generic and biosimilar competition shows a loss of €231 million of net sales on a reported basis. Other parameters may have contributed to the loss of sales, such as a fall in the average selling price of certain products.

The table below sets forth the impact by product.

(€ million)	2021	2020	Change on a reported basis	Change on a reported basis (%)
Aprovel® Europe	87	100	(13)	-13.0%
Lantus® Europe	474	537	(63)	-11.7%
Lovenox® Europe	703	656	47	+7.2%
Plavix® Europe	115	126	(11)	-8.7%
Jevtana® Europe	112	187	(75)	-40.1%
Lantus® United States	861	929	(68)	-7.3%
Lovenox® United States	29	30	(1)	-3.3%
Aprovel® Japan	15	27	(12)	-44.4%
Lantus® Japan	16	21	(5)	-23.8%
Plavix® Japan	75	105	(30)	-28.6%
Total	**2,487**	**2,718**	**(231)**	**-8.5%**

We expect the erosion caused by generic competition to continue in 2022, with a negative impact on our net income. The products likely to be impacted in 2022 include those that already faced generic competition in 2021, but whose sales can reasonably be expected to be subject to further sales erosion in 2022 (see products listed in the table above). In 2022, we may be facing generic competition in some EU countries for Mozobil® following expiry of orphan exclusivity in August 2021 (although a secondary patent and supplementary protection certificate remain in force in the EU).

In 2021, the aggregate consolidated net sales of those products in Europe, the United States and Japan were €2,487 million; this comprised €890 million in the United States (including €861 million in net sales of Lantus®); €1,491 million in Europe; and €106 million in Japan. The negative impact on our 2022 net sales is likely to represent a substantial portion of those sales, but the actual impact will

(1) Non-GAAP financial measure: see definition in "— A.1.6. Presentation of Net Sales" below.
(2) Non-GAAP financial measure: see definition in "— A.1.5. Segment Information — 3. Business Net Income" below.
(3) Non-GAAP financial measure: see definition in "— B. Liquidity and Capital Resources" below.

depend on a number of factors such as the number of generics available, the prices at which the products are sold, and overall market trends, and potential litigation outcomes.

In China, the authorities have implemented a range of healthcare cost containment measures, including a Volume Based Procurement (VBP) program for insulins (see also "Item 4. — B.6.4. Pricing & Reimbursement"). A large number of molecules were selected to submit tenders under successive waves of the VBP program, with the successful bidders being awarded a high level of market share in return for offering lower prices. In 2021, Sanofi successfully tendered for amisulpride and oxaliplatin 50mg, as well as for our insulins Toujeo® and Lantus. As a consequence, Sanofi expects that its glargine sales (Toujeo®/Lantus®) to decrease by around 30% in 2022 in China. Toujeo®/Lantus® net sales in China in 2021 were €459 million.

A.1.3. Purchase accounting effects

Our results of operations and financial condition for the years ended December 31, 2021, and 2020 have been significantly affected by our past acquisitions (acquisition of Aventis in August 2004, acquisition of Genzyme in April 2011, exchange of our Animal Health business (Merial) for Boehringer Ingelheim's Consumer Healthcare business in January 2017, acquisition of Bioverativ in 2018, and certain other transactions). See "— A.1.11. Critical accounting and reporting policies — Business combinations" below for an explanation of the impact of business combinations on our results of operations.

The Bioverativ business combination has generated significant amortization of intangible assets (€320 million in 2021, and €331 million in 2020). The Genzyme business combination has generated significant amortization of intangible assets (€509 million in 2021, and €549 million in 2020). The exchange of Merial for Boehringer Ingelheim's Consumer Healthcare business has generated amortization of intangible assets (€195 million in 2021, and €202 million in 2020).

In order to isolate the purchase accounting effects of all acquisitions and certain other items, we use a non-GAAP financial measure that we refer to as "business net income" (see definition in "— A.1.5. Segment Information — 3. Business Net Income" below).

A.1.4. Sources of revenues and expenses

Revenues. Revenue arising from the sale of goods is presented in the income statement within ***Net sales***. Net sales comprise revenue from sales of pharmaceutical products, consumer health care products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Returns, discounts, incentives and rebates are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. See Note B.13.1. to our consolidated financial statements included at Item 18. of this annual report. We sell pharmaceutical products and vaccines directly, through alliances, and by licensing arrangements throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the contractual arrangements governing those alliances. For more information about our alliances, see "— A.1.7. Financial Presentation of Alliances" below. When our products are sold by licensing arrangements, we receive royalty income that we record in ***Other revenues***. Revenues from non-Sanofi products, mainly comprising royalty income from license arrangements and sales of non-Sanofi products by our US-based entity VaxServe, are presented within Other revenues. This line item also includes revenues arising from the distribution of Eloctate® and Alprolix®) under Sanofi's agreements with Swedish Orphan Biovitrum AB (Sobi) and revenue received under agreements for Sanofi to provide manufacturing services to third parties. See Note B.13.2. to the consolidated financial statements included at Item 18. of this Annual Report on Form 20-F.

Cost of Sales. Our cost of sales consists primarily of the cost of purchasing raw materials and active ingredients, labor and other costs relating to our manufacturing activities, packaging materials, payments made under licensing agreements and distribution costs. We have license agreements under which we manufacture, sell and distribute products that are patented by other companies. When we pay royalties, we record them in ***Cost of sales***.

Operating Income. Our operating income reflects our revenues, our cost of sales and the remainder of our operating expenses, the most significant of which are research and development expenses and selling and general expenses. For our operating segments, we also measure our results of operations through an indicator referred to as "Business Operating Income," which we describe below under "A.1.5. Segment Information — 2/Business Operating Income".

A.1.5. Segment information and Business net income

1/ Operating segments

In accordance with IFRS 8 (Operating Segments), the segment information reported by Sanofi is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the chief operating decision maker. The performance of those segments is monitored individually using internal reports and common indicators. The operating segment disclosures required under IFRS 8 are provided in Notes B.26. and D.35. ("Segment Information") to our consolidated financial statements, included at Item 18. of this annual report.

Sanofi has three operating segments: Pharmaceuticals, Vaccines, and Consumer Healthcare.

The Pharmaceuticals segment comprises, for all geographical territories, the commercial operations of the following global franchises: Specialty Care (Dupixent®, Neurology & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders) and General Medicines (Diabetes, Cardiovascular and Established Prescription Products), together with research, development and production activities dedicated to the Pharmaceuticals segment. This segment also includes associates whose activities are related to pharmaceuticals. Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.1. to our consolidated financial statements for the year ended December 31, 2020). Consequently, the Pharmaceuticals segment no longer includes Sanofi's equity-accounted share of Regeneron's profits for all the periods presented in this Annual Report on Form 20-F.

The Vaccines segment comprises, for all geographical territories, the commercial operations of Sanofi Pasteur, together with research, development and production activities dedicated to vaccines.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for Sanofi's Consumer Healthcare products, together with research, development and production activities dedicated to those products.

Inter-segment transactions are not material.

The costs of Sanofi's global support functions (External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.) are mainly managed centrally at group-wide level. The costs of those functions are presented within the "Other" category. That category also includes other reconciling items such as retained commitments in respect of divested activities.

Following the Capital Markets Day held in February 2021, Sanofi changed the presentation of net sales for certain products in the Pharmaceuticals segment (within the General Medicines GBU) and the Consumer Healthcare segment, and also reallocated certain expenses. In particular, IT costs relating to our new digital organization – previously allocated to the Pharmaceutical, Vaccines, and Consumer Healthcare segments – are now included within the "Other" segment. The 2020 segmental results presented below have been amended for comparative purposes in order to reflect those adjustments.

In accordance with IAS 8, Sanofi has treated the first-time application of the IFRIC agenda decisions on (i) the calculation of provisions for pensions and other post-employment benefits under IAS 19 and (ii) accounting for costs of configuring or customising a supplier's application software in a Software as a Service (SaaS) arrangement as retrospective changes in accounting policy. The impacts of those IFRIC agenda decisions are presented in Note A.2.1. of our consolidated financial statements, included at Item 18. of this annual financial report.

2/ Business operating income

We report segment results on the basis of "Business operating income". This indicator is used internally by Sanofi's chief operating decision maker to measure the performance of each operating segment and to allocate resources. For a definition of "Business operating income", and a reconciliation between that indicator and ***Income before tax and investments accounted for using the equity method***, refer to Note D.35. to our consolidated financial statements.

Our "Business operating income" for 2021 amounted to €10,714 million, versus €9,759 million in 2020, while our "Business operating income margin" was 28.4%, versus 27.1% in 2020. "Business operating income margin" is a non-GAAP financial measure, which we define as the ratio of our "Business operating income" to ***Net sales***.

Our ***Income before tax and investments accounted for using the equity method*** for 2021 amounted to €7,798 million, versus €13,778 million in 2020.

Because our "Business operating income" and "Business operating income margin" are not standardized measures, they may not be directly comparable with the non-GAAP financial measures of other companies using the same or similar non-GAAP financial measures. Although management uses those non-GAAP measures to set goals and measure performance, they have no standardized meaning prescribed by IFRS. These non-GAAP measures are presented solely to permit investors to more fully understand how Sanofi's management assesses underlying performance. These non-GAAP measures are not, and should not be viewed as, a substitute for IFRS measures, and should be viewed in conjunction with our IFRS financials and performance measures. As a result, such measures have limits in their usefulness to investors.

3/ Business net income

We believe that understanding of our operational performance by our management and our investors is enhanced by reporting "Business net income". This non-GAAP financial measure represents "Business operating income", less net financial expenses and the relevant income tax effects.

"Business net income" for 2021 was €8,213 million, 11.8% up on 2020 (€7,346 million), and represented 21.7% of net sales (compared with 20.4% in 2020).

We also report "Business earnings per share" ("Business EPS"), a non-GAAP financial measure we define as "Business net income" divided by the weighted average number of shares outstanding. "Business EPS" was €6.56 for 2021, 11.9% higher than the 2020 figure of €5.86, based on an average number of shares outstanding of 1,252.5 million for 2021 and 1,253.6 million for 2020.

Our ***Net income attributable to equity holders of Sanofi*** amounted to €6,223 million for 2021, compared with €12,294 million in 2020.

The table below reconciles our "Business operating income" to our "Business net income":

(€ million)	December 31, 2021	December 31, 2020 [(a)]
Business operating income	**10,714**	**9,759**
Financial income and expenses	(328)	(335)
Income tax expense	(2,173)	(2,078)
Business net income	**8,213**	**7,346**

(a) Includes the impacts of the IFRIC final agenda decision of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements presented at Item 18. of this annual financial report.

We define "Business net income" as ***Net income attributable to equity holders of Sanofi*** determined under IFRS, excluding the following items:

- amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature);
- fair value remeasurements of contingent consideration relating to business combinations or divestments or acquisition of intangible assets;
- other impacts associated with acquisitions (including impacts relating to investments accounted for using the equity method);
- restructuring costs and similar items (presented within the line item ***Restructuring costs and similar items)***;
- other gains and losses, including gains and losses on major disposals of non-current assets (presented within the line item ***Other gains and losses, and litigation***);
- for 2020, the gain on the divestment of Regeneron shares on May 29, 2020 (see Note D.2. to our consolidated financial statements for the year ended December 31, 2020);
- other costs and provisions related to litigation (presented within the line item ***Other gains and losses, and litigation***);
- the tax effects of the items listed above, and the effects of major tax disputes;
- for 2020, the effects of the discontinuation of accounting by the equity method for the investment in Regeneron (see Note D.2. to our consolidated financial statements for the year ended December 31, 2020); and
- the portion attributable to non-controlling interests of the items listed above.

The table below reconciles our "Business net income" to ***Net income attributable to equity holders of Sanofi***:

(€ million)	2021	2020 [(a)]
Net income attributable to equity holders of Sanofi	**6,223**	**12,294**
Amortization of intangible assets[(b)]	1,580	1,681
Impairment of intangible assets[(c)]	192	330
Fair value remeasurement of contingent consideration	4	(124)
Expenses arising from the impact of acquisitions on inventories	4	53
Restructuring costs and similar items	820	1,089
Other gains and losses, and litigation[(d)]	5	(136)
Gain on divestment of Regeneron shares on May 29, 2020[(e)]	—	(7,225)
Tax effects of the items listed above:	(614)	(270)
• *amortization and impairment of intangible assets*	*(415)*	*(541)*
• *fair value remeasurement of contingent consideration*	*(2)*	*39*
• *expenses arising from the impact of acquisitions on inventories*	—	*(8)*
• *restructuring costs and similar items*	*(200)*	*(299)*
• *gain on divestment of Regeneron shares on May 29, 2020*	—	*477*
• *other tax effects*	*3*	*62*
Share of items listed above attributable to non-controlling interests	(1)	(3)
Investments accounted for using the equity method: restructuring costs and expenses arising from the impact of acquisitions	—	(30)
Effect of discontinuation of equity method for investment in Regeneron[(f)]	—	(313)
Business net income	**8,213**	**7,346**
Average number of shares outstanding (million)	1,252.5	1,253.6
Basic earnings per share (€)	4.97	9.81
Reconciling items per share (€)	1.59	(3.95)
Business earnings per share (€)	6.56	5.86

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements presented at Item 18. of this annual financial report.

(b) Includes amortization expense related to accounting for business combinations: €1,463 million in 2021 and €1,592 million in 2020.

(c) For 2021, this line relates to the discontinuation of the development of sutimlimab in the treatment of Immune Thrombocytopenic Purpura (ITP), and to the termination of various research projects in Vaccines. For 2020, this line mainly comprises impairment losses taken against R&D programs within the Specialty Care GBU, and the discontinuation of certain R&D programs and collaboration agreements in Diabetes.

(d) For 2020, this line mainly comprises the gain on the sale of the Sepraﬁlm® activity to Baxter.

(e) This line includes, for 2020, the gain on the sale of (i) 13 million shares of Regeneron common stock in the registered public offering and (ii) the 9.8 million shares repurchased by Regeneron, but does not include the gain arising from the remeasurement of the 400,000 retained shares at market value as of May 29, 2020.

(f) "Business net income" no longer includes Sanofi's share of profits from its equity investment in Regeneron (see Note D.1. to our consolidated financial statements for the year ended December 31, 2020).

The most significant reconciling items between "Business net income" and ***Net income attributable to equity holders of Sanofi*** relate to (i) the purchase accounting effects of our acquisitions and business combinations, particularly the amortization and impairment of intangible assets (other than software and other rights of an industrial or operational nature) and (ii) the impacts of restructurings or transactions regarded as non-recurring, where the amounts involved are particularly significant. We believe that excluding those impacts enhances an investor's understanding of our underlying economic performance, because it gives a better representation of our recurring operating performance.

We believe that eliminating charges related to the purchase accounting effect of our acquisitions and business combinations (particularly amortization and impairment of some intangible assets) enhances comparability of our ongoing operating performance relative to our peers. Those intangible assets (principally rights relating to research, development and commercialization of products) are accounted for in accordance with IFRS 3 (Business Combinations) and hence may be subject to remeasurement. Such remeasurements are not made other than in a business combination.

We also believe that eliminating the other effects of business combinations (such as the incremental cost of sales arising from the workdown of acquired inventories remeasured at fair value in business combinations) gives a better understanding of our recurring operating performance.

Eliminating restructuring costs and similar items enhances comparability with our peers because those costs are incurred in connection with reorganization and transformation processes intended to optimize our operations.

Finally, we believe that eliminating the effects of transactions that we regard as non-recurring and that involve particularly significant amounts (such as major gains and losses on disposals, and costs and provisions associated with major litigation and other major non-recurring items) improves comparability from one period to the next.

We remind investors, however, that "Business net income" should not be considered in isolation from, or as a substitute for, ***Net income attributable to equity holders of Sanofi*** reported in accordance with IFRS. In addition, we strongly encourage investors and potential investors not to rely on any single financial measure but to review our financial statements, including the notes thereto, carefully and in their entirety.

We compensate for the material limitations described above by using "Business net income" only to supplement our IFRS financial reporting and by ensuring that our disclosures provide sufficient information for a full understanding of all adjustments included in "Business net income".

Because our "Business net income" and "Business EPS" are not standardized measures, they may not be directly comparable with the non-GAAP financial measures of other companies using the same or similar non-GAAP financial measures.

A.1.6. Presentation of net sales

In the discussion below, we present our consolidated net sales for 2021, and 2020. We analyze our net sales by various categories including segment, Global Business Units, franchise, product, and geographical region. In addition to reported net sales, we analyze non-GAAP financial measures designed to isolate the impact on our net sales of currency exchange rates and changes in the structure of our group.

When we refer to changes in our net sales at constant exchange rates (CER), that means that we have excluded the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period.

When we refer to changes in our net sales on a constant structure basis, that means that we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

- by including sales generated by entities or product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we make the acquisition;
- similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and
- for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

A presentation of consolidated net sales for 2020 compared with 2019 is available in our Form 20-F filed on March 4, 2021, Item 5., section "A.2.1. Net Sales".

Following our February 2021 Capital Markets Day, we have changed how we present our sales within the General Medicines and Consumer Healthcare GBUs. We have introduced a separate line for "Industrial sales", which essentially comprises sales of active ingredients and semi-finished products to third parties. Such sales were previously reported within the Diabetes and Cardiovascular & Established Prescription Products franchises on the line for the relevant product, and on the "Generics" line. For the Consumer Healthcare GBU, we have adopted a more granular presentation by introducing new sub-categories that reflect consumer trends and the strengths and opportunities of our portfolio.

A.1.7. Financial presentation of alliances

We have entered into a number of alliances for the development, co-promotion and/or co-marketing of our products. We believe that a presentation of our two principal alliances is useful to an understanding of our financial statements.

The financial impact of the alliances on our income statement is described in "— Results of Operations — Year Ended December 31, 2021 Compared with Year Ended December 31, 2020", in particular in "— Net Sales", "— Other Revenues", "— Share of Profit/Loss from Investments Accounted for using the Equity Method" and "— Net Income Attributable to Non-Controlling Interests".

1/ Alliance arrangements with Regeneron Pharmaceuticals Inc. (Regeneron)

Collaboration agreements on human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed two agreements (amended in November 2009) relating to human therapeutic antibodies: (i) the Discovery and Preclinical Development Agreement, and (ii) the License and Collaboration Agreement, relating to clinical development and commercialization. Under the License and Collaboration Agreement, Sanofi had an option to develop and commercialize antibodies discovered by Regeneron under the Discovery and Preclinical Development Agreement.

Discovery and development

Because Sanofi decided not to exercise its option to extend the Discovery and Preclinical Development Agreement, that agreement expired on December 31, 2017.

As a result of Sanofi's exercise of an option with respect to an antibody under the Discovery and Preclinical Development Agreement, such antibody became a "Licensed Product" under the License and Collaboration Agreement, pursuant to which Sanofi and Regeneron co-develop the antibody with Sanofi initially being wholly responsible for funding the development program. On receipt of the first positive Phase III trial results for any antibody being developed under the License and Collaboration Agreement, the subsequent development costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under the License and Collaboration Agreement are recognized by Sanofi as a reduction in the line item ***Research and development expenses***. Co-development with Regeneron of the antibodies Dupixent®, Kevzara® and REGN3500 (SAR440340 - itepekimab) is ongoing under the License and Collaboration Agreement as of December 31, 2021.

Once a product begins to be commercialized, and provided that the share of quarterly results under the agreement represents a profit, Sanofi is entitled to an additional portion of Regeneron's profit-share (capped at 10% of Regeneron's share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration (see footnote g(ii) to the table provided in Note D.21.1., "Off balance sheet commitments relating to operating activities").

On the later of (i) 24 months before the scheduled launch date or (ii) the first positive Phase III trial results, Sanofi and Regeneron share the commercial expenses of the antibodies co-developed under the License and Collaboration Agreement.

Commercialization

Sanofi is the lead party with respect to the commercialization of all co-developed antibodies, and Regeneron has certain option rights to co-promote the antibodies. Regeneron has exercised its co-promotion rights in the United States and in certain other countries. Sanofi recognizes all sales of the antibodies. Profits and losses arising from commercial operations in the United States are split 50/50. Outside the United States, Sanofi is entitled to between 55% and 65% of profits depending on sales of the antibodies, and bears 55% of any losses. The share of profits and losses due to or from Regeneron under the agreement is recognized within the line items ***Other operating income*** or ***Other operating expenses***, which are components of ***Operating income***.

In addition, Regeneron is entitled to receive payments contingent on the attainment of specified levels of aggregate sales on all antibodies outside the United States, on a rolling twelve-month basis.

A liability for those payments is recognized in the balance sheet when it is highly probable that the specified level of aggregate sales will be met. The opposite entry for that liability is capitalized within ***Other intangible assets*** in the balance sheet. A payment was made in 2021 following the attainment of $1.5 billion of sales of all antibodies outside the United States on a rolling twelve-month basis.

Amendments to the collaboration agreements

In January 2018, Sanofi and Regeneron signed a set of amendments to their collaboration agreements, including an amendment that allowed for the funding of additional programs on Dupixent® and REGN3500 (SAR440340 – itepekimab) with an intended focus on extending the current range of indications, finding new indications, and improving co-morbidity between multiple pathologies.

Effective April 1, 2020, Sanofi and Regeneron signed a Cross License and Commercialization Agreement for Praluent®, whereby Sanofi obtained sole ex-US rights to Praluent®, and Regeneron obtained sole US rights to Praluent® along with a right to 5% royalties on Sanofi's sales of Praluent® outside the United States. Each party is solely responsible for the development, manufacturing and commercialization of Praluent® in their respective territories. Although each company has responsibility for supplying Praluent® in its respective territory, the companies have entered into agreements to support manufacturing needs for each other.

Effective September 30, 2021, Sanofi and Regeneron signed an amendment to their collaboration agreement in order to specify allocations of responsibilities and associated resources between the two parties in connection with the co-promotion of Dupixent® in certain countries. The terms of the collaboration relating to REGN3500 (SAR440340 – itepekimab) are unchanged.

Immuno-oncology (IO) collaboration agreements

On July 1, 2015, Sanofi and Regeneron signed two agreements – the IO Discovery and Development Agreement and the IO License and Collaboration Agreement (IO LCA) – relating to new antibody cancer treatments in the field of immuno-oncology.

The Amended IO Discovery Agreement, effective from December 31, 2018, was terminated through a Letter Amendment dated March 16, 2021 in which Sanofi formalized its opt-out from the BCMAxCD3 and MUC16xCD3 programs.

Libtayo® (cemiplimab)

Under the 2015 IO LCA as amended in January 2018, Sanofi and Regeneron committed funding of no more than $1,640 million, split on a 50/ 50 basis ($820 million per company), for the development of REGN2810 (cemiplimab, trademark Libtayo®), a PD-1 inhibitor antibody. The funding was raised to $1,840 million by way of amendment effective on September 30, 2021. Regeneron is responsible for the commercialization of Libtayo® in the United States, and Sanofi in all other territories. Sanofi has exercised its option to co-promote Libtayo® in the United States. In 2021, Regeneron exercised its option to co-promote Libtayo® in certain other countries.

The IO LCA also provided for a one-time milestone payment of $375 million by Sanofi to Regeneron in the event that sales of a PD-1 product were to exceed, in the aggregate, $2 billion in any consecutive 12-month period.

Under the IO LCA Sanofi and Regeneron share equally in profits and losses in connection with the commercialization of collaboration products, except that Sanofi is entitled to an additional portion of Regeneron's profit-share (capped at 10% of Regeneron's share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties under the IO Discovery Agreement, as amended.

In September 2018, the US Food and Drug Administration (FDA) approved Libtayo® (cemiplimab) for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. Libtayo® is the first and only product specifically approved and available in the United States for advanced stage CSCC. In July 2019, the European Medicines Agency (EMA) granted marketing authorization for Libtayo® for patients with metastatic or locally advanced CSCC who are not candidates for surgery.

In February 2021, the FDA approved Libtayo® for patients with locally advanced basal cell carcinoma (BCC), granted accelerated approval for patients with metastatic BCC, and approved Libtayo® for first-line monotherapy for patients with advanced non-small cell lung cancer (NSCLC) with PD-L1 expression of at least 50%. In June 2021, the EMA approved Libtayo® as a first-line treatment for patients with advanced NSCLC with PD-L1 expression of at least 50% and for advanced basal cell carcinoma. The extensive clinical program for Libtayo® is focused on difficult-to-treat cancers. In skin cancer, this includes trials in adjuvant and neoadjuvant CSCC. Libtayo® is also being investigated in pivotal trials in NSCLC (in combination with chemotherapy) and cervical cancer, as well as in combination with either conventional or novel therapeutic approaches for other solid tumors and blood cancers. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

Investor agreement

In January 2014, Sanofi and Regeneron amended the investor agreement entered into by the two companies in 2007. Under the terms of the amendment, Sanofi accepted various restrictions, including "standstill" provisions that contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron or acquiring more than 30% of Regeneron's capital stock (consisting of the outstanding shares of common stock and the shares of Class A stock). This prohibition remains in place until the earlier of (i) the later of the fifth anniversaries of the expiration or earlier termination of the Zaltrap® collaboration agreement with Regeneron (related to the development and commercialization of Zaltrap®) or the collaboration agreement with Regeneron on monoclonal antibodies (see "Collaboration agreements on human therapeutic antibodies" above), each as amended and (ii) other specified events.

Sanofi also agreed to vote as recommended by Regeneron's Board of Directors, except that it could elect to vote proportionally with the votes cast by all of Regeneron's other shareholders with respect to certain change-of-control transactions, and to vote in its sole discretion with respect to liquidation or dissolution, stock issuances equal to or exceeding 20% of the outstanding shares or voting rights of Regeneron's Class A Stock and Common Stock (taken together), and new equity compensation plans or amendments if not materially consistent with Regeneron's historical equity compensation practices. Sanofi began to account for its interest in Regeneron using the equity method in April 2014. Starting in 2018 Sanofi began to sell a small amount of shares of Regeneron stock pursuant to a Letter Agreement entered into with Regeneron.

On May 29, 2020, Sanofi announced the closing of its sale of 13 million shares of Regeneron common stock in a registered offering and a private sale to Regeneron (see Note D.2.).

At the same date an amendment to the Investor Agreement became effective, which stipulates inter alia that (i) the "standstill" provisions in the Investor Agreement, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron, will continue to apply; (ii) the voting commitments contained in the Investor Agreement will continue to apply to shares held by Sanofi; (iii) Sanofi will no longer have the right to designate an independent board member on the Regeneron Board of Directors.

Pursuant to subsequent sales, as of December 31, 2021 Sanofi held 279,766 shares of Regeneron stock.

2/ Alliance arrangements with Bristol-Myers Squibb (BMS)

Two of Sanofi's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).

On September 27, 2012, Sanofi and BMS signed an agreement relating to their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets.

Under the terms of this agreement, effective January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico ("Territory B"), giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS received royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in Territory B) until 2018, and also received a payment of $200 million from Sanofi in December 2018, part of which is for buying out the non-controlling interests. Rights to Plavix® in Territory B remained unchanged and continued to be governed by the terms of the original agreement until February 28, 2020.

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the new agreement, Sanofi recognized in its consolidated financial statements the revenue and expenses generated by its own operations. Since January 2019 onwards, there has no longer been any share of profits reverting to BMS (previously presented within ***Net income attributable to non-controlling interests*** in the income statement).

In Territory B for Plavix®, which was managed by BMS, the Plavix® business was conducted through the Territory B partnerships, which were jointly owned by BMS and Sanofi. Sanofi recognized its share of profits and losses within the line item ***Share of profit/(loss) from investments accounted for using the equity method***.

On February 28, 2020, Sanofi purchased all BMS's interests (50.1%) in each of the Territory B partnerships for a cumulative purchase price of $12 million. Following a transition period, Sanofi has been commercializing Plavix® under its own label since July 1, 2020.

A.1.8. Impact of exchange rates

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly affected by exchange rate movements between the euro and other currencies, primarily the US dollar and, to a lesser extent, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2021, we earned 38.1% of our net sales in the United States. An increase in the value of the US dollar against the euro has a positive impact on both our revenues and our operating income. A decrease in the value of the US dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A variation in the value of the US dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere.

For a description of arrangements entered into to manage operating foreign exchange risks as well as our hedging policy, see “Item 11. Quantitative and Qualitative Disclosures about Market Risk”, and “Item 3. Key Information — D. Risk Factors — Risks Related to Financial Markets — Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition”.

A.1.9. Divestments

There were no material divestments in 2021.

On May 29, 2020, Sanofi announced the closing of its sale of 13 million shares of Regeneron common stock through a registered offering at a price of $515 per share. This included a previously-announced overallotment option, which was fully exercised by the underwriters. In addition, Sanofi announced the completion of Regeneron's repurchase of 9.8 million shares or approximately $5,000 million in common stock directly from Sanofi. As a result of the offering, Sanofi has sold its entire equity investment in Regeneron (except for 400,000 Regeneron shares retained by Sanofi to support its ongoing collaboration with Regeneron) for total sale proceeds (before transaction-related costs) of €10,575 million. Consequently, Sanofi’s equity interest in Regeneron ceased to be accounted for by the equity method.

On November 26, 2019, Sanofi entered into a definitive agreement to sell Seprafilm® to Baxter. The sale was completed on February 14, 2020. Sanofi recognized a pre-tax gain of €129 million.

For further details about the divestments mentioned above, see Note D.1. to our consolidated financial statements included at Item 18. of this annual report.

A.1.10. Acquisitions

On April 8, 2021, Sanofi acquired the entire share capital of Kymab for an upfront payment of $1.1 billion (€973 million) and up to $350 million (€295 million) contingent upon reaching certain development milestones. The preliminary purchase price allocation resulted in the recognition of €965 million of other intangible assets. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €932 million.

On April 16, 2021, Sanofi completed the public offering for Kiadis. As of the end of the post-closing acceptance period on April 29, 2021, Sanofi held 97.39% of the share capital of Kiadis, and launched a statutory public buy-out procedure in order to obtain 100% of the share capital. The preliminary purchase price allocation resulted in the recognition of €341 million of other intangible assets. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €326 million.

On April 9, 2021, Sanofi acquired Tidal Therapeutics for an upfront payment of $160 million (€136 million), and up to $310 million (€261 million) contingent upon reaching certain development milestones. The preliminary purchase price allocation resulted in the recognition of €130 million of other intangible assets. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €135 million.

On September 14, 2021, Sanofi completed the acquisition of Translate Bio for a purchase price of €2.6 billion. The provisional purchase price allocation resulted in the recognition of goodwill amounting to €2,179 million. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €2,333 million.

On November 9, 2021, Sanofi completed the acquisition of Kadmon in a transaction valued at $1.9 billion (€1.6 billion) on a fully-diluted basis. The preliminary purchase price allocation resulted in the recognition of €1,739 million of other intangible assets. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €1,575 million.

On December 3, 2021, Sanofi completed the acquisition of Origimm Biotechnology GmbH, for an initial payment of €55 million, and up to €95 million contingent upon reaching certain development phases. The preliminary purchase price allocation resulted in the recognition of €55 million of other intangible assets. The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows for the year ended December 31, 2021 is a net cash outflow of €50 million.

On January 23, 2020, Sanofi acquired Synthorx Inc. (“Synthorx”), for $2.5 billion (€2.2 billion). The final purchase price allocation, resulted in the recognition of goodwill amounting to €930 million. Synthorx has no commercial operations, and made a negative contribution of €106 million to Sanofi’s consolidated net income in 2020. The cash outflow on this acquisition amounted to €2,245 million, and was recorded in the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** within the consolidated statement of cash flows.

Sanofi acquired Principia Biopharma Inc. ("Principia") on September 28, 2020, for $3.68 billion (€3.2 billion). The final purchase price allocation resulted in the recognition of goodwill amounting to €912 million. Principia has no commercial operations, and made a negative contribution of €45 million to Sanofi's consolidated net income in 2020. The cash outflow on this acquisition amounted to €2,972 million, and was recorded in the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** within the consolidated statement of cash flows.

For further information about the acquisitions mentioned above, see Notes D.1. and D.2. to our consolidated financial statements included at Item 18. of this Annual Report on Form 20-F.

A.1.11. Critical accounting and reporting policies

Our consolidated financial statements are affected by the accounting and reporting policies that we use. Certain of our accounting and reporting policies are critical to an understanding of our results of operations and financial condition, and in some cases the application of these critical policies can be significantly affected by the estimates, judgments and assumptions made by management during the preparation of our consolidated financial statements. The accounting and reporting policies that we have identified as fundamental to a full understanding of our results of operations and financial condition are the following:

1/ Revenue recognition

Our policies with respect to revenue recognition are discussed in Note B.13. to our consolidated financial statements included at Item 18. of this annual report. Revenue arising from the sale of goods is presented in the income statement within ***Net sales***. ***Net sales*** comprise revenue from sales of pharmaceutical products, consumer healthcare products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. In accordance with IFRS 15 (Revenue from Contracts with Customers), such revenue is recognized when Sanofi transfers control over the product to the customer. Control refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from, the products. For the vast majority of contracts, revenue is recognized when the product is physically transferred, in accordance with the delivery and acceptance terms agreed with the customer.

For contracts entered into by Sanofi Pasteur, transfer of control is usually determined by reference to the terms of release (immediate or deferred) and acceptance of batches of vaccine.

As regards contracts with distributors, Sanofi does not recognize revenue when the product is physically transferred to the distributor in case of products sold on consignment, or if the distributor acts as an agent. In such cases, revenue is recognized when control is transferred to the end customer, and the distributor's commission is presented within the line item ***Selling and general expenses*** in the income statement.

We offer various types of price reductions on our products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with our customers or of specific terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions about the attainment of sales targets. We also estimate the amount of sales returns, on the basis of contractual sales terms and reliable historical data. Discounts, incentives, rebates and sales returns are recognized in the period in which the underlying sales are recognized within ***Net Sales***, as a reduction of gross sales. For additional details regarding the financial impact of discounts, incentives, rebates and sales returns, see Note D.23. to our consolidated financial statements included at Item 18. of this annual report.

Revenues from non-Sanofi products, mainly comprising royalty income from license arrangements and sales of non-Sanofi products by our US-based entity VaxServe, are presented within ***Other revenues***. This line item also includes revenues arising from the distribution of Eloctate® and Alprolix® under Sanofi's agreements with Swedish Orphan Biovitrum AB (Sobi) and revenue received under agreements for Sanofi to provide manufacturing services to third parties.

2/ Business combinations

As discussed in Note B.3. "Business combinations and transactions with non-controlling interests" to our consolidated financial statements included at Item 18. of this annual report, business combinations are accounted for by the acquisition method. The acquiree's identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 (Business Combinations) are measured initially at their fair values as at the acquisition date, except for (i) non-current assets classified as held for sale, which are measured at fair value less costs to sell and (ii) assets and liabilities that fall within the scope of IAS 12 (Income Taxes) and IAS 19 (Employee Benefits). Business combinations completed on or after January 1, 2010 are accounted for in accordance with the revised IFRS 3 and IFRS 10 (Consolidated Financial Statements). In particular, contingent consideration payable to former owners agreed in a business combination, e.g. in the form of payments upon the achievement of certain R&D milestones, is recognized as a liability at fair value as of the acquisition date irrespective of the probability of payment. If the contingent consideration was originally recognized as a liability, subsequent adjustments to the liability are recognized in profit or loss (see Note D.18. "Liabilities related to business combinations and non-controlling interests" to our consolidated financial statements included at Item 18. of this annual report).

3/ Impairment of goodwill and intangible assets

As discussed in Note B.6. "Impairment of property, plant and equipment, intangible assets, and investments accounted for using the equity method" and in Note D.5. "Impairment of intangible assets and property, plant and equipment" to our consolidated financial statements included at Item 18. of this annual report, we test our intangible assets for impairment periodically or when there is any internal or external indication of impairment. Such indicators could include primarily but not exclusively (i) increased market competition resulting from (for example) the introduction of a competitor's product; (ii) earlier than expected loss of exclusivity; (iii) increased pricing pressure; (iv) restrictions imposed by regulatory authorities on the manufacture or sale of a product; (v) delay in the projected launch of a

product; (vi) different from expected clinical trial results; (vii) higher than expected development costs or (viii) lower than expected economic performance.

We test for impairment on the basis of the same objective criteria that were used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset (for its initial valuation) or the carrying amount of the asset (for ongoing tests for impairment).

Significant underlying assumptions requiring the exercise of considerable judgement are applied in the future cash flow projections used to determine the recoverability of intangible assets, including primarily but not exclusively (i) therapeutic class market growth drivers; (ii) expected impacts from competing products (including but not exclusively generics and biosimilars); (iii) projected pricing and operating margin levels; (iv) likely changes in the regulatory, legal or tax environment; and (v) management's estimates of terminal growth or attrition rates.

The recoverable amounts of intangible assets related to research and development projects are determined based on future net cash flows, which reflect the development stage of the project and the associated probability of success of marketization of the compound.

The projected cash flows are discounted to present value using a discount rate which factors in the risks inherent in cash flow projections.

Changes in facts and circumstances, assumptions and/or estimates may lead to future additional impairment losses or reversal of impairment previously recorded.

Key assumptions relating to goodwill impairment are the perpetual growth rate and the post-tax discount rate. A sensitivity analysis to the key assumptions is disclosed in Note D.5. "Impairment of intangible assets and property, plant and equipment" to our consolidated financial statements included at Item 18. of this annual report.

4/ Contingent consideration receivable

As described in Note B.8.1. and D.7.3. to our consolidated financial statements included at Item 18. of this annual report, contingent consideration receivable such as earn-outs on divestments, for example in the form of a percentage of future sales of the acquirer, are recognized as an asset at fair value as of the date of divestment. Subsequent remeasurements of the fair value of the asset are recognized in profit or loss.

5/ Pensions and post-retirement benefits

As described in Note B.23. "Employee benefit obligations" to our consolidated financial statements included at Item 18. of this annual report, we recognize our pension and retirement benefit commitments as liabilities on the basis of an actuarial estimate of the rights vested in employees and retirees at the end of the reporting period, net of the fair value of plan assets held to meet those obligations. We prepare this estimate at least on an annual basis taking into account financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

We recognize all actuarial gains and losses (including the impact of a change in discount rate) immediately through equity.

Depending on the key assumptions used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. A sensitivity analysis to these key assumptions is set forth in Note D.19.1. "Provisions for pensions and other benefits" to our consolidated financial statements included at Item 18. of this annual report.

6/ Taxes

As discussed in Note B.22. "Income tax expense" to our consolidated financial statements included at Item 18. of this annual report, we recognize deferred income taxes on tax loss carry-forwards and on temporary differences between the tax base and carrying amount of assets and liabilities. We calculate our deferred tax assets and liabilities using enacted tax rates applicable for the years during which we estimate that the temporary differences are expected to reverse. We do not recognize deferred tax assets when it is more likely than not that the deferred tax assets will not be realized. The recognition of deferred tax assets is determined on the basis of profit forecasts for each tax group, and of the tax consequences of the strategic opportunities available to Sanofi.

The positions adopted by Sanofi in tax matters are based on its interpretation of tax laws and regulations. Some of those positions may be subject to uncertainty. In such cases, Sanofi assesses the amount of the tax liability on the basis of the following assumptions: that its position will be examined by one or more tax authorities on the basis of all relevant information; that a technical assessment is carried out with reference to legislation, case law, regulations, and established practice; and that each position is assessed individually (or collectively where appropriate), with no offset or aggregation between positions. Those assumptions are assessed on the basis of facts and circumstances existing at the end of the reporting period. When an uncertain tax liability is regarded as probable, it is measured on the basis of Sanofi's best estimate and recognized as a liability; uncertain tax assets are not recognized.

7/ Provisions for risks

Sanofi and its subsidiaries and affiliates may be involved in litigation, arbitration or other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights, compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As discussed in Note B.12. "Provisions for risks" to our consolidated financial statements included at Item 18. of this annual report, we record a provision where we have a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources. We also disclose a contingent liability in circumstances where we are unable to make a reasonable estimate of the expected financial effect that will result from the ultimate resolution of the proceeding, or a cash outflow is not probable.

For additional details regarding the financial impact of provisions for risks see Notes D.19.3. "Other provisions" and D.22. "Legal and Arbitral Proceedings" to our consolidated financial statements included at Item 18. of this annual report.

8/ Provisions for restructuring costs

Provisions for restructuring costs include collective redundancy or early retirement benefits, compensation for early termination of contracts, and rationalization costs relating to restructured sites. Refer to Note D.19.2. to our consolidated financial statements included at Item 18. of this annual report.

Provisions are estimated on the basis of events and circumstances related to present obligations at the end of the reporting period and of past experience, and to the best of management's knowledge at the date of preparation of the financial statements. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from our estimates.

A.2. Results of operations – Year ended December 31, 2021 compared with year ended December 31, 2020

Consolidated income statements

(€ million)	2021	as % of net sales	2020 [(a)]	as % of net sales
Net sales	**37,761**	**100.0%**	**36,041**	**100.0%**
Other revenues	1,414	3.7%	1,328	3.7%
Cost of sales	(12,255)	(32.5%)	(12,159)	(33.7%)
Gross profit	**26,920**	**71.3%**	**25,210**	**69.9%**
Research and development expenses	(5,692)	(15.1%)	(5,530)	(15.3%)
Selling and general expenses	(9,555)	(25.3%)	(9,391)	(26.1%)
Other operating income	859		697	
Other operating expenses	(1,805)		(1,415)	
Amortization of intangible assets	(1,580)		(1,681)	
Impairment of intangible assets	(192)		(330)	
Fair value remeasurement of contingent consideration	(4)		124	
Restructuring costs and similar items	(820)		(1,089)	
Other gains and losses, and litigation	(5)		136	
Gain on Regeneron investment arising from transaction of May 29, 2020	—		7,382	
Operating income	**8,126**	**21.5%**	**14,113**	**39.2%**
Financial expenses	(368)		(388)	
Financial income	40		53	
Income before tax and investments accounted for using the equity method	**7,798**	**20.7%**	**13,778**	**38.2%**
Income tax expense	(1,558)		(1,807)	
Share of profit/(loss) from investments accounted for using the equity method	39		359	
Net income	**6,279**	**16.6%**	**12,330**	**34.2%**
Net income attributable to non-controlling interests	56		36	
Net income attributable to equity holders of Sanofi	**6,223**	**16.5%**	**12,294**	**34.1%**
Average number of shares outstanding (million)	1,252.5		1,253.6	
Average number of shares after dilution (million)	1,257.9		1,260.1	
• Basic earnings per share (€)	4.97		9.81	
• Diluted earnings per share (€)	4.95		9.76	

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements presented at Item 18. of this annual financial report.

A.2.1. Net sales

Consolidated net sales for the year ended December 31, 2021 amounted to €37,761 million, 4.8% higher than in 2020. Exchange rate fluctuations had a negative effect of 2.3 percentage points overall, due mainly to adverse trends in the euro exchange rate against the US dollar, Japanese yen, Turkish lira, Brazilian real and Argentinean peso. At constant exchange rates (CER, see definition below), net sales rose by 7.1%, mainly reflecting strong growth for our Specialty Care global business unit (driven by a solid performance from Dupixent®), and increased sales for our Vaccines business and our Consumer Healthcare global business unit. Those positive effects more than offset a decrease in sales for our General Medicines global business unit, in line with the streamlining of our non-core product portfolio and lower sales of Lantus® and Aprovel®.

Reconciliation of net sales to net sales at constant exchange rates

(€ million)	2021	2020	Change
Net sales	**37,761**	**36,041**	**+4.8%**
Effect of exchange rates	850		
Net sales at constant exchange rates	**38,611**	**36,041**	**+7.1%**

When we refer to changes in our net sales at constant exchange rates (CER), that means that we have excluded the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period.

When we refer to changes in our net sales on a constant structure (CS) basis, that means that we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

- by including sales generated by entities or product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on historical sales information we receive from the party from whom we make the acquisition;
- similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and
- for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

To facilitate analysis and comparisons with prior periods, some figures are given at constant exchange rates and on a constant structure basis (CER/CS).

1/ Net sales by operating segment and global business unit

Our net sales comprise the net sales generated by our Pharmaceuticals, Vaccines and Consumer Healthcare segments.

The table below also presents an analysis of our net sales by Global Business Unit (GBU).

(€ million)	2021	2020	Change on a reported basis	Change at constant exchange rates
Specialty Care GBU	12,752	10,954	+16.4%	+19.7%
General Medicines GBU	14,218	14,720	-3.4%	-1.4%
Pharmaceuticals segment	**26,970**	**25,674**	**+5.0%**	**+7.6%**
Vaccines GBU/segment	**6,323**	**5,973**	**+5.9%**	**+6.8%**
Consumer Healthcare GBU/segment	**4,468**	**4,394**	**+1.7%**	**+4.6%**
Total net sales	**37,761**	**36,041**	**+4.8%**	**+7.1%**

2/ Net sales by franchise, geographical region and product

Following our February 2021 Capital Markets Day, we have changed how we present our sales within the General Medicines and Consumer Healthcare GBUs. We have introduced a separate line for “Industrial sales”, which essentially comprises sales of active ingredients and semi-finished products to third parties. Such sales were previously reported within the Diabetes and Cardiovascular & Established Prescription Products franchises on the line for the relevant product, and on the “Generics” line. For the Consumer Healthcare GBU, we have adopted a more granular presentation by introducing new sub-categories that reflect consumer trends and the strengths and opportunities of our portfolio.

For comparative purposes, the 2020 figures used to compute the year-on-year movements presented below have been adjusted to reflect those changes.

(€ million)	Net sales	Change (CER)	Change (reported)	United States	Change (CER)	Europe	Change (CER)	Rest of the world	Change (CER)
Dupixent®	**5,249**	**+52.7%**	**+48.5%**	**3,971**	**+46.2%**	**649**	**+67.4%**	**629**	**+90.0%**
Aubagio®	1,955	-1.8%	-4.4%	1,312	-5.7%	512	+8.0%	131	+6.5%
Lemtrada®	82	-24.8%	-27.4%	35	-38.3%	24	-20.0%	23	+4.3%
Kevzara®	287	+23.7%	+21.6%	135	+12.2%	102	+34.7%	50	+39.5%
Total Neurology & Immunology	**2,324**	**-0.3%**	**-2.9%**	**1,482**	**-5.5%**	**638**	**+10.0%**	**204**	**+13.0%**
Cerezyme®	683	+3.9%	-1.0%	173	+1.1%	244	-2.0%	266	+11.4%
Cerdelga®	254	+11.1%	+8.5%	132	+7.0%	105	+14.1%	17	+28.6%
Myozyme®/Lumizyme®	1,003	+7.7%	+5.8%	373	+8.1%	410	+5.1%	220	+12.0%
Fabrazyme®	844	+6.5%	+3.3%	395	+1.0%	223	+11.0%	226	+12.8%
Aldurazyme®	243	+7.3%	+3.8%	54	+5.8%	84	+5.0%	105	+9.8%
Total Rare Diseases	**3,126**	**+7.0%**	**+3.8%**	**1,142**	**+5.4%**	**1,069**	**+5.6%**	**915**	**+10.5%**
Jevtana®	455	-12.3%	-15.1%	253	+6.5%	112	-40.6%	90	-5.8%
Fasturtec®	152	+2.0%	—%	90	-3.1%	46	+9.5%	16	+14.3%
Libtayo®	129	+91.0%	+92.5%	—	—	105	+72.1%	24	+283.3%
Sarclisa®	176	+318.6%	+309.3%	67	+165.4%	64	+600.0%	45	+500.0%
Total Oncology	**912**	**+16.9%**	**+14.3%**	**410**	**+15.2%**	**327**	**+8.7%**	**175**	**+40.5%**
Alprolix®	414	-7.9%	-11.2%	332	+7.5%	—	—	82	-41.8%
Eloctate®	563	-8.5%	-11.8%	429	+0.4%	—	—	134	-29.0%
Cablivi®	164	+47.8%	+45.1%	81	+16.7%	81	+95.1%	2	—
Total Rare Blood Disorders	**1,141**	**-3.0%**	**-6.2%**	**842**	**+4.5%**	**81**	**+95.1%**	**218**	**-33.6%**
Specialty Care GBU	**12,752**	**+19.7%**	**+16.4%**	**7,847**	**+20.1%**	**2,764**	**+19.0%**	**2,141**	**+19.3%**
Lantus®	2,494	-3.8%	-6.3%	861	-3.8%	474	-11.9%	1,159	-0.3%
Toujeo®	969	+6.4%	+3.9%	259	+0.4%	394	+5.1%	316	+13.7%
Soliqua®/Suliqua®	195	+24.2%	+21.1%	115	+19.0%	29	+20.8%	51	+40.5%
Other Diabetes	877	-3.7%	-6.3%	183	-6.0%	257	-3.7%	437	-2.8%
Total Diabetes	**4,535**	**-0.8%**	**-3.3%**	**1,418**	**-1.8%**	**1,154**	**-4.2%**	**1,963**	**+2.0%**
Lovenox®	1,486	+12.0%	+10.0%	29	+3.3	703	+7.5%	754	+16.8%
Plavix®	929	+2.4%	+1.8%	9	—	115	-8.7%	805	+4.2%
Multaq®	329	+8.3%	+5.4%	292	+9.9%	22	-8.3%	15	+7.1%
Praluent®	218	-15.8%	-15.8%	5	-94.3%	161	+34.5%	52	+52.9%
Aprovel®	419	-24.5%	-24.4%	10	-54.5%	87	-13.0%	322	-25.7%
Mozobil®	233	+10.7%	+8.9%	129	+8.1%	60	+9.1%	44	+22.2%
Thymoglobulin®	350	+13.3%	+10.8%	207	+12.6%	34	+17.2%	109	+13.5%
Generics	699	-7.7%	-13.5%	117	-23.6%	7	-20.0%	575	-3.5%
Other Established Prescription Products	4,212	-4.5%	-6.2%	380	+0.3%	1,371	-10.3%	2,461	-1.8%
Total Cardiovascular & Established Prescription Products	**8,875**	**-1.8%**	**-3.7%**	**1,178**	**-6.7%**	**2,560**	**-3.2%**	**5,137**	**+0.1%**
Industrial Sales	**808**	**+0.5%**	**-0.6%**	**41**	**-35.8%**	**723**	**+10.8%**	**44**	**-48.9%**
General Medicines GBU	**14,218**	**-1.4%**	**-3.4%**	**2,637**	**-4.8%**	**4,437**	**-1.4%**	**7,144**	**—%**
Total Pharmaceuticals	**26,970**	**+7.6%**	**+5.0%**	**10,484**	**+12.7%**	**7,201**	**+5.5%**	**9,285**	**+3.9%**
Polio/Pertussis/Hib Vaccines	2,159	+4.2%	+2.5%	470	+18.4%	306	-7.6%	1,383	+2.7%
Adult Booster Vaccines	488	+6.0%	+4.5%	279	+16.2%	146	-3.3%	63	-10.0%
Meningitis/Pneumonia Vaccines	658	+21.1%	+17.7%	487	+28.8%	1	—%	170	+3.0%
Influenza Vaccines	2,628	+5.9%	+6.3%	1,366	-13.6%	729	+64.4%	533	+16.4%
Travel & Other Endemics Vaccines	306	+3.3%	+1.7%	86	+20.5%	42	-10.6%	178	—%
Total Vaccines	**6,323**	**+6.8%**	**+5.9%**	**2,762**	**+1.6%**	**1,225**	**+25.6%**	**2,336**	**+5.0%**
Allergy	612	+2.9%	-0.8%	371	+7.5%	49	-3.9%	192	-3.4%
Cough, Cold and Flu	320	-15.2%	-16.0%	—	—%	156	-22.0%	164	-7.7%
Pain	1,093	+7.2%	+4.0%	196	+12.2%	515	+7.5%	382	+4.6%
Digestive Wellness	1,131	+17.6%	+14.5%	124	+51.8%	389	+4.9%	618	+21.1%
Physical Wellness	323	-5.2%	-6.4%	—	—%	29	+7.4%	294	-6.3%
Mental Wellness	211	+12.5%	+9.9%	46	+9.3%	100	+12.2%	65	+15.3%
Personal Care	519	+3.5%	-0.2%	394	+5.1%	4	+33.3%	121	-2.3%
Other	259	-11.0%	-13.7%	8	-33.3%	91	-33.8%	160	+11.2%
Total Consumer Healthcare	**4,468**	**+4.6%**	**+1.7%**	**1,139**	**+10.6%**	**1,333**	**-1.8%**	**1,996**	**+5.7%**
Total Sanofi	**37,761**	**+7.1%**	**+4.8%**	**14,385**	**+10.3%**	**9,759**	**+6.6%**	**13,617**	**+4.4%**

3/ Net sales – Pharmaceuticals segment

In 2021, net sales for the Pharmaceuticals segment amounted to €26,970 million, up 5.0% on a reported basis and 7.6% at constant exchange rates (CER). The year-on-year reported-basis increase of €1,296 million reflects adverse exchange rate effects of €666 million, and the following principal effects at constant exchange rates:

- solid performances from Dupixent® (+€1,862 million), the Oncology (+€135 million) and Rare Diseases (+€210 million) franchises, and industrial sales (+€4 million); and
- lower sales for the Cardiovascular & Established Prescription Products (-€166 million), Diabetes (-€38 million), Rare Blood Disorders (-€37 million) and Neurology & Immunology (-€8 million) franchises.

Comments on the performances of our major Pharmaceuticals segment products are provided below.

Specialty Care GBU

Dupixent®

Dupixent® (developed in collaboration with Regeneron) generated net sales of €5,249 million in 2021, up 48.5% on a reported basis and 52.7% at constant exchange rates. In the United States, sales of Dupixent® reached €3,971 million in 2021, boosted by continuing strong demand in the treatment of atopic dermatitis in adults, adolescents and children aged 6 to 11 years (approved in May 2020), plus ongoing adoption of the product for the treatment of asthma and nasal polyps. In Europe, the product posted 2021 net sales of €649 million, up 67.4% CER, driven by continuing growth in atopic dermatitis in key markets and by new launches in asthma. In the Rest of the World region, Dupixent® posted net sales of €629 million (+90.0% CER), including €291 million in Japan (+61.5% CER). In China, where Dupixent® was approved in June 2020 for moderate to severe atopic dermatitis in adults and was added to the NRDL (National Reimbursement Drug List) in March 2021, the product generated net sales of €74 million (+483.3% CER).

Neurology and immunology

In 2021, the **Neurology and Immunology** franchise generated net sales of €2,324 million, down 2.9% on a reported basis and 0.3% CER, with growth in sales of Kevzara® more than offset by lower sales of Lemtrada® and Aubagio®.

Aubagio® posted net sales of €1,955 million in 2021, down 1.8% CER, on lower sales in the United States (-5.7% CER at €1,312 million) reflecting increased competition, which was partly offset by growth in Europe (+8.0% CER at €512 million) and the Rest of the World region (+6.5% CER at €131 million).

In 2021, net sales of **Lemtrada®** amounted to €82 million, down 24.8% CER, on a decline in sales in the United States (-38.3% CER at €35 million) and Europe (-20.0% CER at €24 million).

Net sales of **Kevzara®** (developed in collaboration with Regeneron) in 2021 reached €287 million, up 23.7% CER, driven by sales of the product in Europe (+34.7% CER at €102 million), the Rest of the World region (+39.5% CER at €50 million), and the United States (+12.2% CER at €135 million). The growth trend mainly reflects rising demand for IL-6 receptor inhibitors, and temporary shortages of tocilizumab.

Rare diseases

In 2021, net sales for the **Rare Diseases** franchise totaled €3,126 million, up 3.8% on a reported basis and 7.0% at constant exchange rates (CER). In Europe, net sales for the franchise rose by 5.6% CER to €1,069 million. In the United States, net sales advanced by 5.4% CER to €1,142 million. In the Rest of the World region, net sales were up 10.5% CER at €915 million.

Net sales of the **Pompe disease franchise** (Myozyme®/Lumizyme® and Nexviazyme®) were up 9.5% CER in 2021 at €1,020 million, driven (i) in the United States by Lumizyme® sales growth (+8.1% CER at €373 million) and the launch of Nexviazyme® (€15 million), and (ii) by the increases in Europe (5.7% CER, at €412 million) and in the Rest of the World region (+12.5% CER at €220 million). Growth in all three geographies was due to a rise in the number of patients diagnosed with and treated for Pompe disease.

In 2021, net sales for the **Gaucher disease** franchise (**Cerezyme®** and **Cerdelga®**) reached €937 million, a rise of 5.7% CER. Cerezyme® sales were up 3.9% CER at €683 million, helped by a solid performance in the Rest of the World region (+11.4% CER at €266 million). Sales of Cerdelga® rose by 11.1% CER to €254 million, driven by Europe (+14.1% CER at €105 million), the United States (+7.0% CER at €132 million) and the Rest of the World region (28.6% CER at €17 million) as new patients adopted the product or switched treatment.

Net sales of the **Fabry disease** treatment **Fabrazyme®** in 2021 were €844 million (+6.5% CER), propelled by Europe (+11.0% CER at €223 million) and the Rest of the World region (+12.8% CER at €226 million), and to a lesser extent by the United States (+1.0% CER at €395 million), due to more patients adopting the product and better observance of the treatment.

Oncology

In 2021, net sales for the **Oncology** franchise amounted to €912 million, up 14.3% on a reported basis and 16.9% CER, driven by the launches of Sarclisa® and Libtayo®, which more than offset the impact of generics of Jevtana® in Europe.

Jevtana® posted net sales of €455 million in 2021, down 12.3% CER, as sales decreased in Europe (-40.6% CER at €112 million) following the entry of generic competition in some European markets at end March 2021. In the US, where the Jevtana® composition of matter patent expired in September 2021, sales were up 6.5% CER at €253 million. However, Sanofi has filed patent infringement suits against generic filers on Jevtana® under Hatch-Waxman in the U.S. District Court for the District of Delaware asserting three method of use patents, two of which (US 10,583,110 and US 10,716,777) expire in October 2030 and the other one of which (US 8,927,592) expires in April 2031 including 6-month pediatric exclusivities. Sanofi has reached settlement agreements with some of the defendants and the suit against the remaining defendants is ongoing. No trial dates have been scheduled and the remaining defendants have agreed not to launch any generic cabazitaxel product until the earlier of a district court decision in favor of the defendants or four months after the completion of the post-trial briefing. Separately, Jevtana® has been granted a data exclusivity on the CARD clinical study results which expires in December 2023.

Libtayo® (developed in collaboration with Regeneron) reported net sales of €129 million in 2021, up 91.0% CER, driven by rising demand in cutaneous squamous cell carcinoma (CSCC) and by launches in new countries. In the United States, Libtayo® sales are consolidated by Regeneron under the terms of the alliance between Sanofi and Regeneron (see Note C.1. "Alliance arrangements with Regeneron Pharmaceuticals, Inc. (Regeneron)" to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F).

In 2021, net sales of **Sarclisa®** reached €176 million, up 318.6% CER, driven by new launches in European countries and a good performance in Japan; sales for the year were €67 million in the United States, €64 million in Europe, and €45 million in the Rest of the World region.

Rare blood disorders

In 2021, the **Rare Blood Disorders** franchise generated net sales of €1,141 million, down 6.2% on a reported basis and 3.0% at constant exchange rates, mainly as a result of lower industrial sales to Sobi following amendments to the supply agreement in 2020. When excluding that effect, net sales rose by 8.0% CER.

Eloctate®, indicated in the treatment of hemophilia A, generated net sales of €563 million in 2021, down 8.5% CER, reflecting lower sales in the Rest of the World region (-29.0% CER) due to a decrease in industrial sales to Sobi (which are recorded in that region). Excluding industrial sales to Sobi, net sales of Eloctate® increased by 0.4% in 2021.

In 2021, net sales of **Alprolix®**, indicated in the treatment of hemophilia B, amounted to €414 million, down 7.9% CER. In the United States, sales of the product reached €332 million, up 7.5% CER, reflecting patient switching to prophylactic treatments. In the Rest of the World region, net sales of Alprolix® were down 41.8% CER at €82 million, due to a decrease in industrial sales to Sobi (which are recorded in that region). Excluding industrial sales to Sobi, net sales of Alprolix® increased by 7.8% in 2021.

Cablivi®, which treats acquired thrombotic thrombocytopenic purpura (aTTP) in adults, posted net sales of €164 million in 2021, up 47.8% CER, reflecting increased awareness of the condition and of the treatment along with new guidelines on aTTP from the International Society on Thrombosis and Haemostasis (ISTH). Sales reached €81 million in the United States (+16.7% CER), while in Europe net sales were up 95.1% CER at €81 million, mainly as a result of launches in new countries.

General Medicines GBU

In 2021, General Medicines GBU net sales were down slightly year-on-year by 1.4% at €14,218 million. Following the February 2021 Capital Markets Day, Sanofi decided to prioritize core products within its General Medicines portfolio that have differentiated or established profiles and significant opportunity for growth in key markets; these include Toujeo®, Soliqua®, Praluent®, Multaq®, Lovenox®, Plavix®. and Thymoglobulin®. Sales of core products in 2021 were up 5.6% CER at €5,768 million, fueled by good performances from Lovenox®, Mozobil®, Thymoglobulin® and Toujeo®. Non-core products posted sales of €7,642 million, down 6.2% CER, reflecting a streamlining of the portfolio and lower sales of Lantus® and Aprovel®/Avapro®. In 2021 industrial sales, mainly comprising sales of active ingredients and semi-finished products to third parties, rose by 0.5% CER to €808 million.

Diabetes

In 2021, net sales for the **Diabetes** franchise were €4,535 million, down 3.3% on a reported basis and 0.8% at constant exchange rates. This mainly reflects a decrease in sales for the franchise in the United States (-1.8% CER at €1,418 million) and Europe (-4.2% CER at €1,154 million) on lower sales of Lantus®, and a decrease in sales of Amaryl® in China.

Net sales of **Lantus®** in 2021 were down 3.8% CER at €2,494 million. In the United States, the product saw net sales decrease by 3.8% CER to €861 million, due largely to a drop in the average net selling price. In Europe, net sales of Lantus® were €474 million (-11.9% CER), reflecting competition from biosimilars of insulin glargine and patients switching to Toujeo®. In the Rest of the World region, net sales of Lantus® held relatively steady in 2021 at €1,159 million.

In 2021, **Toujeo®** posted net sales of €969 million, up 6.4% CER, driven by the Rest of the World region (+13.7% CER at €316 million, due mainly to the product's launch in China in the fourth quarter of 2020) and by Europe (+5.1% CER at €394 million, reflecting patient switches from Lantus® and a favorable comparative base. During 2021, Sanofi successfully tendered for Toujeo® and Lantus® under China's national volume-based procurement (VBP) program, thereby securing significant sales volumes but at lower prices. As a consequence Sanofi expects a decrease in sales of insulin glargines (Toujeo® and Lantus®) in China by around 30% in 2022. Toujeo®/ Lantus® net sales in China in 2021 were €459 million. In the United States, net sales of Toujeo® were relatively stable year-on-year (+0.4% at €259 million), as volume growth offset the effect of lower average selling prices.

Net sales of **Soliqua®** rose by 24.2% CER in 2021 to €195 million. Sales increased in all geographies, especially the Rest of the World region (+40.5% CER at €51 million, reflecting a number of product launches) and the United States (+19.0% CER at €115 million).

Cardiovascular & Established Prescription Products

In 2021, net sales for the **Cardiovascular & Established Prescription Products** amounted to €8,875 million, down 3.7% on a reported basis and 1.8% at constant exchange rates. A positive performance from core products such as Lovenox®, Plavix®, Thymoglobulin® and Mozobil® was more than offset by lower sales of Praluent®, Aprovel®/Avapro® and generics, and by the impact of divestments of non-core products.

Net sales of **Lovenox®** were €1,486 million in 2021, up 12.0% CER, driven by sales growth in the Rest of the World region (+16.8% CER at €754 million), as the effect of recent WHO recommendations on the use of low molecular weight heparins in hospitalized COVID-19 patients more than offset the impact of competition from biosimilars.

Net sales of **Plavix®** were €929 million in 2021, up 2.4% CER, as sales growth in the Rest of the World region (+4.2%, driven by China where sales were up 11.1% CER at €389 million) more than offset reduced sales in Japan and Europe.

Net sales of **Aprovel®/Avapro®** were €419 million, down 24.5% CER, mainly due to lower sales in China (-20.0% CER at €157 million) as a result of temporary supply constraints.

In 2021, net sales of **Praluent®** (developed in collaboration with Regeneron) decreased by 15.8% CER to €218 million, reflecting lower sales in the United States (-94.3% CER at €5 million). Since April 1, 2020, as a result of the restructuring of Sanofi's collaboration

agreements with Regeneron (see Note C.1. "Alliance arrangements with Regeneron Pharmaceuticals Inc. (Regeneron)" to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F), Sanofi has had sole responsibility for Praluent® outside the United States, while Regeneron has had sole responsibility for Praluent® in the United States. The two companies entered into agreements to meet short-term manufacturing imperatives. Since then, sales of Praluent® in the United States recognized by Sanofi correspond to industrial sales made to Regeneron. The reduction in sales in the United States was partly offset by sales growth in Europe (+34.5% CER at €161 million) and the Rest of the World region (+52.9% CER at €52 million), following the launch of the product in China in the second quarter of 2020. Praluent® was added to the Chinese National Reimbursement Drug List (NRDL) in January 2022.

Net sales of **Multaq®** totaled €329 million in 2021, up 8.3% CER, as growth in US sales stimulated by increased medical consultations and prescriptions for antiarrhythmic drugs with the recovery from the COVID-19 pandemic more than offset lower sales in Europe.

4/ Net sales – Vaccines segment/GBU

In 2021, the Vaccines segment posted net sales of €6,323 million, up 5.9% on a reported basis and 6.8% CER, reflecting growth across all franchises; the main drivers were influenza vaccines (+5.9% CER at €2,628 million), Polio/Pertussis/Hib vaccines (+4.2% CER at €2,159 million), and a recovery of sales of meningitis vaccines (+21.1% CER at €658 million).

Sales of **influenza vaccines** rose by 5.9% CER in 2021 to €2,628 million. This reflected strong demand in Europe, boosted by increased sales of differentiated vaccines (especially in Germany, supported by the adoption of a recommendation of Efluelda® as the vaccine of choice for people aged over 60 years), and also in the Rest of the World region (+16.4% CER at €533 million); those effects were partly offset by lower sales in the United States (-13.6% at €1,366 million).

In 2021, **Polio/Pertussis/Hib (PPH) vaccines** generated net sales of €2,159 million, up 4.2% CER, reflectring growth in the United States (+18.4% CER at €470 million) due to a favorable ordering sequence for Pentacel® and a soft comparative from 2020. Sales in the Rest of the World region rose by 2.7% CER to €1,383 million, boosted by Pentaxim® in China. In Europe, net sales of PPH vaccines were down 7.6% CER at €306 million.

Vaxelis™, a vaccine co-developed in an alliance between Sanofi and Merck, has been available in the United States since June 2021. Vaxelis™ is the first and only hexavalent combined vaccine approved in the United States to protect infants and children against six diseases: diphtheria, tetanus, pertussis, polio, hepatitis B, and invasive diseases caused by Hemophilus Influenzae type b. Finished product sales of Vaxelis™ are consolidated by the MSP Vaccine Company joint venture.

Net sales of **Meningitis/Pneumonia vaccines** for 2021 were €658 million, up 21.1% CER, driven by the United States (+28.8% CER at €487 million) due to the resumption of meningitis vaccinations and the launch of MedQuadfi® in March 2021. Sales in the Rest of the World region were 3.0% higher CER at €170 million.

In 2021, sales of **adult booster vaccines** advanced by 6.0% to €488 million, mainly due to a recovery in Adacel® vaccinations in the United States.

Net sales of **travel and other endemics vaccines** in 2021 were €306 million, a rise of 3.3% CER, reflecting a low comparable base in 2020 due to the COVID-19 pandemic.

5/ Net sales – Consumer Healthcare segment/GBU

In 2021, net sales for the **Consumer Healthcare** (CHC) segment increased by 1.7% on a reported basis and 4.6% at constant exchange rates to €4,468 million. Stronger sales in the Digestive Wellness, Pain, and Mental Wellness categories more than offset the effects of low incidence of coughs and colds during the winter season and of divestments of non-core products.

In the **United States**, CHC net sales amounted to €1,139 million in 2021, up 10.6% CER, boosted by strong growth in the Digestive Wellness, Pain, Mental Wellness, Personal Care and Allergy categories.

In **Europe**, CHC net sales were down 1.8% CER in 2021 at €1,333 million; this reflects lower sales in the Cough & Cold categories, due to social distancing and divestments of non-core strategic brands.

In the **Rest of the World** region, CHC net sales were up 5.7% CER at €1,996 million in 2021. The main factor was growth in the Digestive Wellness category, driven by Enterogermina®, Buscopan® and Essentiale®, plus higher sales in the Pain and Mental Wellness categories.

6/ Net sales by geographical region

The table below sets forth our net sales for 2021 and 2020 by geographical region:

(€ million)	2021	2020	Change on a reported basis	Change at constant exchange rates
United States	14,385	13,465	+6.8%	+10.3%
Europe	9,759	9,151	+6.6%	+6.6%
Rest of the World	13,617	13,425	+1.4%	+4.4%
of which China	2,720	2,454	+10.8%	+7.9%
of which Japan	1,657	1,735	-4.5%	+1.7%
of which Brazil	815	836	-2.5%	+7.3%
of which Russia	575	641	-10.3%	-4.8%
Total net sales	**37,761**	**36,041**	**+4.8%**	**+7.1%**

In 2021, net sales in the **United States** reached €14,385 million, up 6.8% on a reported basis and 10.3% at constant exchange rates. Strong performances from Dupixent® (+46.2% CER at €3,971 million) and meningitis vaccines (+28.8% CER at €487 million) more than offset lower sales of influenza vaccines (-13.6% CER at €1,366 million), of Praluent® (-94.3% CER at €5 million, following the restructuring of Sanofi's collaboration agreements with Regeneron; see Note C.1. "Alliance arrangements with Regeneron Pharmaceuticals Inc. (Regeneron)" to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F), and from our Neurology & Immunology franchise (-5.5% CER at €1,482 million.

In **Europe**, net sales advanced by 6.6% on a reported basis and 6.6% at constant exchange rates in 2021 to €9,759 million. A substantial rise in sales of influenza vaccines (+64.4% CER at €729 million), plus strong performances by Dupixent® (+67.4% CER at €649 million), Libtayo® (+72.1% CER at €105 million) and Sarclisa® (+600.0% CER at €64 million), more than offset lower sales for the Diabetes franchise (-4.2% CER at €1,154 million) and the Cardiovascular & Established Prescription Products franchise (-3.2% CER at €2,560 million).

In the **Rest of the World** region, net sales for 2021 increased by 1.4% on a reported basis and 4.4% at constant exchange rates, to €13,617 million. Under-performances by the Rare Blood Disorders franchise (mainly due to lower industrial sales to Sobi further to the amendments to the supply agreement in 2020) and by Aprovel® were outweighed by good performances from Dupixent®, Lovenox®, influenza vaccines and the Rare Diseases franchise. China led the way in terms of growth, with net sales up 7.9% CER at €2,720 million, driven by an acceleration in sales for the Cardiovascular & Established Prescription Products franchise and Dupixent®.

A.2.2. Other income statement items

In accordance with IAS 8, Sanofi has treated the first-time application of the IFRIC agenda decisions on (i) the calculation of provisions for pensions and other post-employment benefits under IAS 19 and (ii) accounting for costs of configuring or customising a supplier's application software in a Software as a Service (SaaS) arrangement as retrospective changes in accounting policy. The impacts of those IFRIC agenda decisions are presented in Note A.2.1. to our consolidated financial statements, included at Item 18. of this annual financial report.

1/ Other revenues

Other revenues increased by 6.5% to €1,414 million in 2021 (versus €1,328 million in 2020). This line item mainly comprises VaxServe sales of non-Sanofi products (€1,078 million in 2021 versus €1,136 million in 2020, recorded within the Vaccines segment). It also includes, among other items, royalties associated with the distribution of Eloctate® and Alprolix® under our agreements with Swedish Orphan Biovitrum AB (Sobi) and revenue received under agreements for Sanofi to provide manufacturing services to third parties.

2/ Gross profit

Gross profit for 2021 amounted to €26,920 million compared with €25,210 million in 2020, an increase of 6.8%. Gross margin (the ratio of gross profit to net sales) also rose, reaching 71.3% in 2021, versus 69.9% in 2020. The year-on-year increase in gross margin reflects a stronger gross margin for the Pharmaceuticals segment, which reached 75.2% in 2021, versus 73.3% in 2020, driven largely by productivity gains in Industrial Affairs and the favorable effect of the increased weighting of Specialty Care in the sales mix. This increase was partly offset by lower gross margin for (i) the Vaccines segment, at 63.1% in 2021 (versus 63.7% in 2020), due in particular to the impact of the destruction of time-expired vaccine inventories as a result of the COVID-19 pandemic, and (ii) the Consumer Healthcare segment, at 65.3% in 2021 (versus 66.6% in 2020).

3/ Research and development expenses

Research and development (R&D) expenses amounted to €5,692 million in 2021, versus €5,530 million in 2020, a rise of 2.9%. The increase in R&D expenditures in 2021 was mainly due to additional investments in Immunology and Oncology, while cost control effort continues. R&D expenses represented 15.1% of net sales in 2021, versus 15.3% in 2020.

4/ Selling and general expenses

Selling and general expenses amounted to €9,555 million in 2021 (25.3% of net sales), compared with €9,391 million in 2020 (26.1% of net sales), representing a slight increase of 1.7% in line with increased promotional spend in Specialty Care. The reduction in the ratio of selling and general expenses to net sales was due to close control over general expenses, and operational excellence.

5/ Other operating income and expenses

Other operating income amounted to €859 million in 2021 (versus €697 million in 2020), and other operating expenses to €1,805 million, versus €1,415 million in 2020.

Overall, this represented a net expense of €946 million in 2021, compared with a net expense of €718 million in 2020.

(€ million)	2021	2020 [(a)]	Change
Other operating income	859	697	+162
Other operating expenses	(1,805)	(1,415)	-390
Other operating income/(expenses), net	**(946)**	**(718)**	**-228**

(a) Includes the impacts of the IFRIC final agenda decision of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements presented at Item 18. of this annual financial report.

The overall negative change of €228 million was due mainly to higher net expenses relating to our pharmaceutical alliance partners, and in particular an increase in the share of profits/losses generated by the alliance with Regeneron under our collaboration agreement (see Note C.1. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F), due mainly to higher sales of Dupixent®.

The contribution of our alliance with Regeneron to this line item is as follows:

(€ million)	2021	2020
Income & expense related to (profit)/loss sharing under the Monoclonal Antibody Alliance	(1,253)	(727)
Additional share of profit paid by Regeneron towards development costs	127	75
Reimbursement to Regeneron of selling expenses incurred	(303)	(349)
Total: Monoclonal Antibody Alliance	**(1,429)**	**(1,001)**
Immuno-Oncology Alliance	**68**	**89**
Other (mainly Zaltrap®)	**(12)**	**(14)**
Other operating income/(expenses), net related to the Regeneron Alliance	**(1,373)**	**(926)**

"Other operating income/expenses, net" includes gains on asset divestments (€418 million in 2021, €307 million in 2020), and in 2021 a payment of €119 million received from Daiichi Sankyo relating to the ending of a vaccines collaboration agreement in Japan.

6/ Amortization of intangible assets

Amortization charged against intangible assets amounted to €1,580 million in 2021, compared with €1,681 million in 2020.

This €101 million decrease was mainly due to products reaching the end of their amortization periods.

7/ Impairment of intangible assets

For 2021, this line item shows net impairment losses of €192 million taken against intangible assets, mainly related to the discontinuation of the development of sutimlimab (Immune Thrombocytopenic Purpura (ITP)), and the termination of various research projects in Vaccines.

For 2020, this line item shows net impairment losses of €330 million taken against intangible assets, mainly on R&D projects in Specialty Care and the termination of various R&D projects and collaboration agreements in Diabetes, in line with the strategic roadmap unveiled in December 2019.

8/ Fair value remeasurement of contingent consideration

Fair value remeasurements of contingent consideration recognized in acquisitions represented a net gain of €4 million in 2021, versus a net gain of €124 million in 2020.

The net gain for 2020 mainly related to the contingent consideration receivable further to the dissolution of the Sanofi Pasteur MSD joint venture (net gain of €89 million).

9/ Restructuring costs and similar items

Restructuring costs and similar items represented a total charge of €820 million in 2021, versus a charge of €1,089 million in 2020.

The amount charged in 2021 includes employee-related expenses of €193 million and net expenses, gains and losses on assets (including asset write-downs and accelerated depreciation and amortization) of €110 million. In addition, those restructuring costs and similar items relate to transformational projects, primarily those associated with the creation of the new standalone Consumer Healthcare entity and of EUROAPI (the future European market leader in active pharmaceutical ingredients), and with the implementation of Sanofi's new digital strategy.

Restructuring costs and similar items represented a total charge of €1,089 million in 2020. That amount includes (i) employee-related expenses of €697 million, comprising separation costs (primarily in Europe) further to the announcement of plans to adapt Sanofi's organization in line with the new "Play to Win" strategy and (ii) net expenses, gains and losses on assets (including asset write-downs and accelerated deprecation and amortization) of €149 million.

10/ Other gains and losses, and litigation

For 2021, this line item shows a net loss of €5 million.

For 2020, this line item shows a net gain of €136 million, mainly due to a gain on the sale of operations related to the Seprafilm® activity.

11/ Operating income

Operating income amounted to €8,126 million in 2021, versus €14,113 million in 2020. The reduction was mainly due to the recognition in 2020 of the €7,382 million gain on the divestment of Sanofi's equity investment in Regeneron following the transaction of May 29, 2020. Without this effect, operating income would have increased year-on-year, reflecting the improvement in gross profit and lower restructuring costs.

12/ Financial income and expenses

Net financial expenses were €328 million in 2021, versus €335 million in 2020, a slight decrease of €7 million.

The cost of our net debt (see the definition in "B. Liquidity and Capital Resources" below) increased to €259 million in 2021, compared with €225 million in 2020, largely due to a reduction in net gains on interest rate and currency derivatives used to hedge debt to €51 million in 2021, compared with €66 million in 2020.

Other movements in net financial expenses included:

- the net change in "Other financial income and expenses" (income of €16 million in 2021, versus expense of €4 million in 2020); and
- a reduction in the net interest cost of pension plans, mainly in France and Germany (€44 million, versus €57 million in 2020).

13/ Income before tax and investments accounted for using the equity method

Income before tax and investments accounted for using the equity method reached €7,798 million in 2021, versus €13,778 million in 2020.

14/ Income tax expense

Income tax expense represented €1,558 million in 2021, versus €1,807 million in 2020, giving an effective tax rate based on consolidated net income of 20.0% in 2021, compared with 13.1% in 2020. The reduction in income tax expense was mainly due to the tax effects of the transaction involving Regeneron shares in 2020.

The effective tax rate on our business net income is a non-GAAP financial measure (see definition under "A.1.5. Segment information — 3. Business Net Income" above). It is calculated on the basis of business operating income, minus net financial expenses and before (i) the share of profit/loss from investments accounted for using the equity method and (ii) net income attributable to non-controlling interests. We believe the presentation of this measure, used by our management, is also useful for investors as it provides a means to analyze the effective tax cost of our current business activities. It should not be seen as a substitute for the effective tax rate based on consolidated net income.

When calculated on business net income, our effective tax rate was 20.9% in 2021, compared with 22.0% in 2020.

The table below reconciles our effective tax rate based on consolidated net income to our effective tax rate based on business net income:

(as a percentage)	2021	2020 [(a)]
Effective tax rate based on consolidated net income	**20%**	**13.1%**
Tax effects:		
Amortization and impairment of intangible assets	0.5	1.3
Restructuring costs and similar items	0.4	1.1
Gain on sale of Regeneron shares on May 29, 2020	—	6.9
Other tax effects	—	(0.4)
Effective tax rate based on business net income	**20.9%**	**22.0%**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements presented at Item 18. of this annual financial report.

15/ Share of profit/(loss) from investments accounted for using the equity method

Investments accounted for using the equity method contributed net income of €39 million in 2021, versus €359 million in 2020. For 2020, this line item mainly comprised our share of profits from Regeneron (€343 million in 2020). On May 29, 2020, Sanofi sold its entire equity investment in Regeneron (except for 400,000 Regeneron shares retained by Sanofi to support its ongoing collaboration with Regeneron), which then ceased to be accounted for by the equity method. The amount for 2020 therefore reflects the use of the equity method until that date.

16/ Net income

Net income amounted to €6,279 million in 2021, compared with €12,330 million in 2020.

17/ Net income attributable to non-controlling interests

Net income attributable to non-controlling interests was €56 million in 2021, versus €36 million in 2020.

18/ Net income attributable to equity holders of Sanofi

Net income attributable to equity holders of Sanofi amounted to €6,223 million in 2021, compared with €12,294 million in 2020.

Basic earnings per share for 2021 was €4.97 versus €9.81 for 2020, based on an average number of shares outstanding of 1,252.5 million in 2021 and 1,253.6 million in 2020. Diluted earnings per share for 2021 was €4.95 versus €9.76 for 2020, based on an average number of shares after dilution of 1,257.9 million in 2021 and 1,260.1 million in 2020.

A.2.3. Segment results

Our business operating income, as defined in Note D.35. ("Segment information") to our consolidated financial statements, amounted to €10,714 million in 2021, compared with €9,759 million in 2020, an increase of 9.8%. That represents 28.4% of our net sales, compared with 27.1% in 2017.

The table below sets forth our business operating income for the years ended December 31, 2021 and 2020:

(€ million)	December 31, 2021	December 31, 2020 [a]	Change
Pharmaceuticals	9,409	9,207	+2.2%
As percentage of sales	*34.9 %*	*+35.9%*	
Vaccines	2,609	2,336	+11.7%
As percentage of sales	*41.3 %*	*+39.1%*	
Consumer Healthcare	1,493	1,410	+5.9%
As percentage of sales	*33.4 %*	*+32.1%*	
Other	(2,797)	(3,194)	-12.4%
Business operating income	**10,714**	**9,759**	**+9.8%**

(a) 2020 figures have been adjusted to take account of the reallocation of certain expenses (in particular IT costs related to Sanofi's new digital organization) from the Pharmaceuticals, Vaccines and Consumer Healthcare operating segments to the "Other" segment.
(b) Includes the impacts of the IFRIC final agenda decision of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements presented at Item 18. of this annual financial report.

B. Liquidity and capital resources

Our operations generate significant positive cash flows. We fund our day-to-day investments (with the exception of significant acquisitions) primarily with operating cash flow, and pay regular dividends on our shares.

"Net debt" is a non-GAAP financial indicator which is reviewed by our management, and which we believe provides useful information to measure our overall liquidity and capital resources. We define "net debt" as (i) the sum total of short term debt, long term debt, and interest rate derivatives and currency derivatives used to manage debt, minus (ii) the sum total of cash and cash equivalents and interest rate derivatives and currency derivatives used to manage cash and cash equivalents. Lease liabilities are not included in net debt.

As of December 31, 2021 our net debt was €9,983 million, compared with €8,790 million as of December 31, 2020. The increase was due largely to cash outflows of €5,594 million on acquisitions of consolidated entities and to the €4,008 million dividend payout to our shareholders, partly offset by the €8,096 million of free cash flow generated in the year.

In order to assess our financing risk, we also use the "gearing ratio", a non-GAAP financial measure (see table in section "B.2. Consolidated Balance Sheet and Debt" below). We define the gearing ratio as the ratio of net debt to total equity. As of December 31, 2021, our gearing ratio was 14.5%, compared with 13.9% as of December 31, 2020.

Because our net debt and gearing ratio are not standardized measures, they may not be directly comparable with the non-GAAP financial measures of other companies using the same or similar non-GAAP financial measures. Despite the use of non-GAAP measures by management in setting goals and measuring performance, these are non-GAAP measures that have no standardized meaning prescribed by GAAP.

B.1. Consolidated statement of cash flows

Generally, factors that affect our earnings – for example, pricing, volume, costs and exchange rates – flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and vaccines. Receipts of royalty payments also contribute to cash from operations.

Summarized consolidated statements of cash flows

(€ million)	2021	2020 [a]
Net cash provided by/(used in) operating activities	10,522	7,418
Net cash provided by/(used in) investing activities	(7,298)	3,619
Net cash provided by/(used in) financing activities	(7,056)	(6,485)
Impact of exchange rates on cash and cash equivalents	15	(64)
Net change in cash and cash equivalents	**(3,817)**	**4,488**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements presented at Item 18. of this annual financial report.

Net cash provided by/used in operating activities represented a net cash inflow of €10,522 million in 2021, compared with €7,418 million in 2020. This increase mainly resulted from an improvement in operating cash flow before changes in working capital (which amounted to €9,113 million in 2021, versus €7,743 million in 2020) and a net reduction of €1,409 million in the working capital requirement in 2021, versus a net increase of €325 million in 2020.

Net cash provided by/used in investing activities represented a net cash outflow of €7,298 million in 2021, compared with a net inflow of €3,619 million in 2020. The net cash outflow in 2021 was attributable mainly to the acquisitions of Translate Bio (€2,333 million), Kadmon (€1,575 million), Kymab (€932 million), Kiadis (326 million), Tidal (€135 million) and Origimm (€50 million).The net cash inflow in 2020 was mainly due to the sale of Renegeron shares on May 29, 2020 for cash proceeds of €10,370 million, partly offset by cash outflows related to the acquisitions of Synthorx (€2,245 million) and Principia (€2,972 million).

Acquisitions of property, plant and equipment and intangible assets amounted to €2,043 million, versus €2,083 million in 2020. There were €1,479 million of acquisitions of property, plant and equipment (versus €1,254 million in 2020), most of which (€1,024 million) related to the Pharmaceuticals segment, primarily in industrial facilities. The Vaccines segment accounted for €382 million of acquisitions of property, plant and equipment during 2021. Acquisitions of intangible assets (€564 million, versus €829 million in 2020) mainly comprised contractual payments for intangible rights under license and collaboration agreements.

After-tax proceeds from disposals amounted to €718 million in 2021, and included the divestments of (i) two activities related to some of our established prescription products for a selling price before taxes of €187 million and (ii) some of our Consumer Healthcare products for a selling price before taxes of €109 million. In 2020, after-tax proceeds from disposals amounted to €918 million, the main items being (i) the sale to Baxter of the Seprafilm® activity for a selling price before taxes of €311 million; (ii) the divestment of some of our established prescription products for €97 million before taxes; and (iii) €167 million before taxes of contingent consideration received in connection with a past divestment.

Net cash provided by/used in financing activities represented a net cash outflow of €7,056 million in 2021, compared with a net cash outflow of €6,485 million in 2020. The 2021 figure includes a net outflow of €2,804 million for debt repayments (including lease liabilities), primarily (i) the redemption at maturity on March 29, 2021 of the $2 billion bond issue from March 2011 and (ii) the early redemption on June 22, 2021 of the €500 million bond issue from September 2015; that compares with a net outflow of €1,885 million for debt repayments in 2020). It also includes the dividend payout to our shareholders of €4,008 million (versus €3,937 million in 2020), and the effect of changes in our share capital (repurchases of our own shares, net of capital increases), representing a net cash outflow of €196 million in 2021 and a net cash inflow of €619 million in 2020.

The ***net change in cash and cash equivalents*** in 2021 was an increase of €3,817 million, versus an increase of €4,488 million in 2020.

"Free cash flow" for the year ended December 31, 2021 was €8,096 million, an increase on the 2020 figure of €6,982 million. This reflects our operational performance (including the effect of cost containment measures), and asset divestments made during the period.

"Free cash flow" is a non-GAAP financial indicator which is reviewed by our management, and which we believe provides useful information to measure the net cash generated from our operations that is available for strategic investments[(1)] (net of divestments[(1)]), for debt repayment, and for payments to shareholders. "Free cash flow" is determined from our "Business net income"[(2)] after adding back (in the case of expenses and losses) or deducting (in the case of income and gains) the following items: depreciation, amortization and impairment, share of undistributed earnings from investments accounted for using the equity method, gains & losses on disposals, net change in provisions including pensions and other post-employment benefits, deferred taxes, share-based payment expense and other non-cash items. It also includes net changes in working capital, capital expenditures and other asset acquisitions[(3)] net of disposal proceeds[(3)], and payments related to restructuring and similar items. "Free cash flow" is not defined by IFRS, and is not a substitute for ***Net cash provided by operating activities*** as reported under IFRS. Management recognizes that the term "Free cash flow" may be interpreted differently by other companies and under different circumstances.

The table below sets forth a reconciliation between ***Net cash provided by operating activities*** and "Free cash flow":

(€ million)	2021	2020 [(a)]
Net cash provided by operating activities	**10,522**	**7,418**
Acquisitions of property, plant and equipment and software	(1,400)	(1,329)
Acquisitions of intangible assets, equity interests and other non-current financial assets[(b)]	(1,488)	(562)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax[(b)]	667	930
Repayments of lease liabilities[(c)]	(149)	(234)
Other items[(d)]	(56)	759
Free cash flow	**8,096**	**6,982**

(a) Includes the impacts of the IFRIC final agenda decision of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1. to the consolidated financial statements presented at Item 18. of this annual financial report.
(b) Free cash flow includes investments and divestments not exceeding a cap of €500 million per transaction.
(c) Cash outflows relating to repayments of the principal portion of lease liabilities (IFRS 16) are included in free cash flow.
(d) This line mainly comprises in 2020 the reclassification of net foreign exchange gains and losses arising on financial monetary items, and on the related hedging instruments, to Net cash provided by/(used in) financing activities.

B.2. Consolidated balance sheet and debt

In accordance with IAS 8, Sanofi has treated the first-time application of the IFRIC agenda decisions on (i) the calculation of provisions for pensions and other post-employment benefits under IAS 19 and (ii) accounting for costs of configuring or customising a supplier's application software in a Software as a Service (SaaS) arrangement as retrospective changes in accounting policy. The impacts of those IFRIC agenda decisions are presented in Note A.2.1. of our consolidated financial statements, included at Item 18. of this annual financial report.

Total assets were €120,242 million as of December 31, 2021, compared with €114,413 million as of December 31, 2020, an increase of €5,829 million.

Net debt was €9,983 million as of December 31, 2021, versus €8,790 million as of December 31, 2020. The increase was due largely to cash outflows of €5,594 million on acquisitions of consolidated entities and to the €4,008 million dividend payout to our shareholders, partly offset by the €8,096 million of free cash flow generated in the year.

(1) Above a cap of €500 million per transaction.
(2) Non-GAAP financial measure, as defined in "— A.1.5. — Segment Information — 3. Business Net income" above.
(3) Not exceeding a cap of €500 million per transaction.

"Net debt" is a non-GAAP financial measure which is reviewed by our management, and which we believe provides useful information to measure our overall liquidity and capital resources. We define "net debt" as (i) the sum total of short term debt, long term debt, and interest rate derivatives and currency derivatives used to manage debt, minus (ii) the sum total of cash and cash equivalents and interest rate derivatives and currency derivatives used to manage cash and cash equivalents.

(€ million)	2020	2019
Long-term debt	17,123	19,745
Short-term debt and current portion of long-term debt	3,183	2,767
Interest rate and currency derivatives used to manage debt	(56)	119
Total debt	**20,250**	**22,631**
Cash and cash equivalents	(10,098)	(13,915)
Interest rate and currency derivatives used to manage cash and cash equivalents	(169)	74
Net debt[(a)]	**9,983**	**8,790**
Total equity	69,031	63,252
Gearing ratio	**14.5%**	**13.9%**

(a) Net debt does not include lease liabilities, which amounted to €2,108 million as of December 31, 2021 and €1,163 million as of December 31, 2020.

To assess our financing risk, we use the "gearing ratio", a non-GAAP financial measure. This ratio (which we define as the ratio of net debt to total equity) increased from 13.9% as of December 31, 2020 to 14.5% as of December 31, 2021. Analyses of debt as of December 31, 2021 and December 31, 2020, by type, maturity, interest rate and currency, are provided in Note D.17.1. to our consolidated financial statements.

We expect that the future cash flows generated by our operating activities will be sufficient to repay our debt. The financing arrangements in place as of December 31, 2021 at the Sanofi parent company level are not subject to covenants regarding financial ratios and do not contain any clauses linking fees to Sanofi's credit rating.

Other key movements in the balance sheet are described below.

Total **equity** was €69,031 million as of December 31, 2021, versus €63,252 million as of December 31, 2020. The year-on-year change reflects the following principal factors:

- increases: our net income for 2021 (€6,279 million); and positive currency translation differences (€2,459 million); and
- decreases: the dividend paid to our shareholders in respect of the 2020 financial year (€4,008 million), and repurchases of our own shares (€382 million).

As of December 31, 2021, we held 11.02 million of our own shares, recorded as a deduction from equity and representing 0.872% of our share capital.

Goodwill and ***Other intangible assets*** (€69,463 million in total) increased by €6,758 million year-on-year, the main factors being:

- increases: movements associated with the acquisitions of Translate Bio (€2,179 million of provisional goodwill, €396 million of other intangible assets), Kymab (€965 million of other intangible assets), and Kadmon (€1,739 million of other intangible assets), and currency translation differences (€2,398 million); and
- decreases: amortization and impairment charged in the period (€1,932 million).

Investments accounted for using the equity method (€250 million) increased by €49 million due to the remeasurement of our interest in the MSP Vaccine Company joint venture.

Other non-current assets amounted to €3,127 million, a year-on-year increase of €393 million. This mainly reflects the $180 million equity investment in Owkin, and the recognition as of December 31, 2021 of overfundings of defined-benefit pension schemes (especially in the United Kingdom).

Net deferred tax assets amounted to €2,981 million as of December 31, 2021, versus €2,406 million as of December 31, 2020, a year-on-year rise of €575 million. This mainly reflects deferred taxes arising on consolidation adjustments for intragroup margin in inventory, and an increase in tax loss carry-forwards.

Non-current provisions and other non-current liabilities (€6,721 million) showed a decrease of €594 million, mainly related to actuarial losses on defined-benefit plans (recognized in Other comprehensive income).

Liabilities related to business combinations and to non-controlling interests (€714 million) were €109 million higher year-on-year. The main movements in this line item during 2021 were the recognition of $382 million of contingent consideration payable to Shire Human Genetic Therapies Inc. (Shire) as a result of our acquisition of Translate Bio in September 2021, partly offset by the settlement during the first half of 2021 of the contingent consideration liability due to True North Therapeutics as a result of our acquisition of Bioverativ.

B.3. Liquidity

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements, in both the short term (i.e. the 12 months following the year ended December 31, 2021) and the long term (i.e. beyond such additional 12-month period). At year-end 2021, we held cash and cash equivalents amounting to €10,098 million, substantially all of which were held in euros (see Note D.13. to our consolidated financial statements included at Item 18. of this annual report). As at December 31, 2021, €427 million of our cash and cash equivalents were held by captive insurance and reinsurance companies in accordance with insurance regulations.

We run the risk of delayed payments or even non-payment by our customers, who consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies (see "Item 3.D. Risk Factors — 2. Risks Relating to Our Business — We are subject to the risk of non-payment by our customers"). Deteriorating credit and economic conditions and other factors in some countries have resulted in, and may continue to result in an increase in the average length of time taken to collect our accounts receivable in these countries. Should these factors continue, it may require us to re-evaluate the collectability of these receivables in future periods. We carefully monitor sovereign debt issues and economic conditions and evaluate accounts receivable in these countries for potential collection risks. We have been conducting an active recovery policy, adapted to each country and including intense communication with customers, negotiations of payment plans, charging of interest for late payments, and legal action. Over our business as a whole, the amount of trade receivables overdue by more than 12 months (which primarily consists of amounts due from public sector bodies) decreased from €95 million as of December 31, 2020 to €56 million as of December 31, 2021 (see Note D.10. to our consolidated financial statements).

At year-end 2021, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities amounted to a total of €8,000 million at December 31, 2021. For a discussion of our treasury policies, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

We expect that cash from our operations will be sufficient to repay our debt. For a discussion of our liquidity risks, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

C. Off balance sheet arrangements/Contractual obligations and other commercial commitments

We have various contractual obligations and other commercial commitments arising from our operations. Our contractual obligations and our other commercial commitments as of December 31, 2021 are shown in Notes D.3., D.17., D.18., and D.21. to our consolidated financial statements included at Item 18. of this annual report. Note D.21. to our consolidated financial statements discloses details of commitments under our principal research and development collaboration agreements. For a description of the principal contingencies arising from certain business divestitures, refer to Note D.22.d.) to our 2021 consolidated financial statements.

Sanofi's contractual obligations and other commercial commitments are set forth in the table below

December 31, 2021		Payments due by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Future contractual cash flows relating to debt and debt hedging instruments[(a)]	21,677	3,271	4,618	5,117	8,671
Principal payments related to lease liabilities[(b)]	2,336	314	476	362	1,184
Other lease obligations (with a term of less than 12 months, low value asset leases and lease contracts committed but not yet commenced)[(c)]	109	39	16	18	36
Irrevocable purchase commitments[(d)]					
• given	8,901	5,343	1,784	685	1,089
• received	(1,124)	(366)	(442)	(166)	(150)
Research & development license agreements					
• Commitments related to R&D and other commitments	536	254	169	77	36
• Potential milestone payments[(e)]	2,892	237	1,139	451	1,065
Obligations relating to business combinations[(f)]	689	108	181	78	322
Estimated benefit payments on unfunded pensions and post employment benefits[(g)]	1,106	60	105	106	835
Total contractual obligations and other commitments	**37,122**	**9,260**	**8,046**	**6,728**	**13,088**
Undrawn general-purpose credit facilities	8,000	4,000	—	4,000	—

(a) See Note D.17.1. to our consolidated financial statements, included at Item 18. of this annual report.
(b) See Note D.17.2. to our consolidated financial statements, included at Item 18. of this annual report.
(c) See Note D.21.1. to our consolidated financial statements, included at Item 18. of this annual report.
(d) These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments (see Note D.3. to our consolidated financial statements, included at Item 18. of this annual report) and (ii) goods and services.
(e) This line includes all potential milestone payments on projects regarded as reasonably possible, i.e. on projects in the development phase.
(f) See Note D.18. to our consolidated financial statements, included at Item 18. of this annual report.
(g) See Note D.19.1. to our consolidated financial statements, included at Item 18. of this annual report. The table above does not include ongoing annual employer's contributions to plan assets, estimated at €49 million for 2022.

We may have payments due to our current or former research and development partners under collaboration agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaboration partner a fee and receive intellectual property rights to the product in exchange. We are also generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license agreements, joint development, co-marketing and other contractual arrangements. In addition to

upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

Because of the uncertain nature of development work, it is impossible to predict (i) whether Sanofi will exercise further options for products, or (ii) whether the expected milestones will be achieved, or (iii) the number of compounds that will reach the relevant milestones. It is therefore impossible to estimate the maximum aggregate amount that Sanofi will actually pay in the future under existing collaboration agreements.

Given the nature of its business, it is highly unlikely that Sanofi will exercise all options for all products or that all milestones will be achieved.

The main collaboration agreements relating to development projects are described in Note D.21.1. to our consolidated financial statements, included at Item 18. of this annual report. Milestone payments relating to development projects under these agreements included in the table above exclude projects still in the research phase (€6.7 billion in 2021, and €6.7 billion in 2020) and payments contingent upon the attainment of sales targets once a product is on the market (€8.1 billion in 2021, and €8.1 billion in 2020).

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Since January 1, 2007, Sanofi has separated the offices of Chairman and Chief Executive Officer. Annual evaluations conducted since that date have indicated that this governance structure is appropriate to Sanofi's current configuration. This arrangement was maintained with the appointment of Serge Weinberg to the office of Chairman firstly on May 17, 2010, then on May 6, 2011, again on May 4, 2015, and finally on April 30, 2019. The Board of Directors believes this governance structure is still appropriate to the current context in which Sanofi operates and its share ownership structure, and as protecting the rights of all of its stakeholders.

The **Chairman** organizes and directs the work of the Board, and is responsible for ensuring the proper functioning of the corporate decision-making bodies in compliance with good governance principles. The Chairman coordinates the work of the Board of Directors with that of its Committees. He ensures that the Company's management bodies function properly, and in particular that the directors are able to fulfil their duties. The Chairman is accountable to the Shareholders' General Meeting, which he chairs.

In addition to these roles conferred by law, the Chairman:

- in coordination with the Chief Executive Officer, liaises between the Board of Directors and the shareholders of the Company;
- is kept regularly informed by the Chief Executive Officer of significant events and situations affecting the affairs of the Company, and may request from the Chief Executive Officer any information useful to the Board of Directors;
- may, in close collaboration with the Chief Executive Officer, represent the Company in high-level dealings with governmental bodies and with key partners of the Company and/or of its subsidiaries, both nationally and internationally;
- seeks to prevent any conflict of interest and manages any situation that might give rise to a conflict of interest. He also gives rulings, in the name of the Board, on requests to take up external directorships of which he may become aware or that may be submitted to him by a director;
- may interview the statutory auditors in preparation for the work of the Board of Directors and the Audit Committee; and
- strives to promote in all circumstances the values and image of the Company.

The Chairman is also required to develop and maintain a proper relationship of trust between the Board and the Chief Executive Officer, so as to ensure that the latter consistently and continuously implements the orientations determined by the Board.

In fulfilling his remit, the Chairman may meet with any individual, including senior executives of the Company, while avoiding any involvement in directing the Company or managing its operations, which are exclusively the responsibility of the Chief Executive Officer.

Finally, the Chairman reports to the Board on the fulfilment of his remit.

The Chairman carries out his duties during the entire period of his term of office, subject to the caveat that a director who is a natural person may not be appointed or reappointed once that director has reached the age of 70.

The **Chief Executive Officer** manages the Company, and represents it in dealings with third parties within the limit of the corporate purpose. The Chief Executive Officer has the broadest powers to act in all circumstances in the name of the Company, subject to the powers that are attributed by law to the Board of Directors and to the Shareholders' General Meeting and within the limits set by the Board of Directors.

The Chief Executive Officer must be less than 65 years old.

Limitations on the powers of the Chief Executive Officer set by the Board

With effect from March 6, 2018, the limitations on the powers of the Chief Executive Officer are specified in the Board Charter. Without prejudice to legal provisions regarding authorizations that must be granted by the Board (regulated agreements, guarantees, divestments of equity holdings or real estate, etc.), prior approval from the Board of Directors is required for transactions or decisions resulting in an investment or divestment, or an expenditure or guarantee commitment, made by the Company and its subsidiaries, in excess of:

- a cap of €500 million (per transaction) for transactions, decisions or commitments pertaining to a previously approved strategy; and
- a cap of €150 million (per transaction) for transactions, decisions or commitments not pertaining to a previously approved strategy.

When such transactions, decisions or commitments give rise to installment payments to the contracting third party (or parties) that are contingent upon future results or objectives, such as the registration of one or more products, attainment of the caps is calculated by aggregating the various payments due from signature of the contract until (and including) filing of the first application for marketing authorization in the United States or in Europe.

Attainment of the above caps is also assessed after taking into account all commitments to make payments on exercise of a firm or conditional option with immediate or deferred effect, and all guarantees or collateral to be provided to third parties over the duration of such commitments.

The prior approval procedure does not apply to transactions and decisions that result in the signature of agreements that solely involve subsidiaries and the Company itself.

Board of Directors

The Board of Directors establishes the orientation of the Company's activities and ensures that they are implemented, paying due consideration to social and environmental issues. Subject to those powers expressly attributed to Shareholders' General Meetings and within the limits set by the corporate purpose, it addresses any issue of relevance to the proper conduct of the Company's affairs and, through its deliberations, settles matters concerning the Company.

Each year, the Board of Directors conducts a review to ensure that there is an appropriate balance in its composition and in the composition of its Committees. In particular, the Board seeks to ensure gender balance and a broad diversity of competencies, experiences, nationalities and ages, reflecting our status as a diversified global business. The Board investigates and evaluates not only potential candidates, but also whether existing directors should seek reappointment. Above all, the Board seeks directors who show independence of mind and are competent, dedicated and committed, with compatible and complementary personalities.

As of December 31, 2021 our Board of Directors had 15 members, including two directors representing employees. 54% of the directors (excluding directors representing employees) were women, and 53% of the directors (including directors representing employees) were non-French nationals.

Acting on proposals from the Chief Executive Officer and in liaison with the Compensation Committee and the Appointments, Governance and CSR Committee, the Board sets objectives for gender balance on Sanofi's executive bodies, and more generally ensures that an inclusion (non-discrimination) and diversity policy is applied within the Company. As of December 31, 2021, 27% of the 11 Executive Committee members were women, and 73% were non-French nationals. Following the changes announced on July 29, 2021 and implemented on October 1, 2021 and February 1, 2022, as of the date of publication of this Annual Report on Form 20-F, 18% of our Executive Committee members were 18% women and 73% were non-French nationals. For more details on these changes, see the section entitled "Executive Committee" below.

The Board of Directors is also kept informed, in particular on the occasion of its annual discussion on equal opportunity and equal pay policy, on how Sanofi's inclusion and diversity policy is cascaded down to "Senior Leaders" and "Executives" (the positions in Sanofi with the highest level of responsibility).

Finally, the Board monitors progress on our CSR strategy, as recalibrated in 2021, paying particularly close attention to tracking delivery on our CSR program including our climate commitments. Since 2020, 15% of the variable compensation package of our CEO has been linked to CSR criteria, including an objective to cut our greenhouse gas emissions.

The rules and operating procedures of our Board of Directors are defined by law, by our Articles of Association, and by our Board Charter (an English language version of which is reproduced in full as Exhibit 1.2 to this Annual Report on Form 20-F).

Term of Office

The term of office of directors is four years. Directors are required to seek reappointment by rotation, such that members of the Board are required to seek reappointment on a regular basis in the most equal proportions possible. Exceptionally, the Shareholders' Ordinary General Meeting may appoint a director to serve for a term of one, two or three years, in order to ensure adequate rotation of Board members. Each director standing down is eligible for reappointment. Should one or more directorships fall vacant as a result of death or resignation, the Board of Directors may make provisional appointments in the period between two Shareholders' General Meetings, in accordance with applicable laws.

Directors may be removed from office at any time by a Shareholders' General Meeting.

A natural person cannot be appointed or reappointed as a director once he or she reaches the age of 70. As soon as the number of directors aged over 70 represents more than one-third of the directors in office, the oldest director shall be deemed to have resigned; his or her term of office shall end at the date of the next Shareholders' Ordinary General Meeting.

Selection Process for Board Members

The Appointments, Governance and CSR Committee has a remit to organize a procedure for selecting future independent directors. Once the desired profile and skillset for a new director has been defined, a search for potential candidates is conducted by external consultants.

Once a shortlist has been established, the Committee interviews two or three candidates. After completing the interviews, the Committee makes a recommendation to the Board on the candidate with the best fit for the profile, supporting that recommendation with an explanation of how the interviews were conducted and giving reasons why a candidate was selected.

Independence of Board Members

Under the terms of the AFEP-MEDEF corporate governance code (the AFEP-MEDEF Code), a director is independent when he or she has no relationship of any kind whatsoever with the Company, its group or its senior management that may color his or her judgment. More specifically, a director can only be regarded as independent if he or she:

- is not (and has not been during the past five years):
  - an employee or executive officer of the Company,
  - an employee, executive officer or director of an entity consolidated by the Company, or
  - an employee, executive officer or director of the Company's parent, or of an entity consolidated by that parent (criterion 1);
- is not an executive officer of an entity in which (i) the Company directly or indirectly holds a directorship or (ii) an employee of the Company is designated as a director or (iii) an executive officer of the Company (currently, or who has held office within the past five years) holds a directorship (criterion 2);

- is not a customer, supplier, investment banker or corporate banker that is material to the Company or its group, or for whom the Company or its group represents a significant proportion of its business (criterion 3);
- has no close family ties with a corporate officer of the Company (criterion 4);
- has not acted as auditor for the Company over the course of the past five years (criterion 5);
- has not been a director of the Company for more than twelve years (criterion 6);
- does not receive variable compensation in cash or in the form of shares or any compensation linked to the performance of the Company or its group (criterion 7); or
- does not represent a shareholder that has a significant or controlling interest in the Company (criterion 8).

The influence of other factors such as the ability to understand challenges and risks, and the courage to express ideas and form a judgment, is also evaluated before it is decided whether a director can be regarded as independent.

In compliance with our Board Charter and pursuant to the AFEP-MEDEF Code, the Board of Directors' meeting of February 22, 2022 discussed the independence of the current directors. Of the fifteen directors in office on that date, nine were deemed to be independent directors by reference to the independence criteria used by the Board of Directors pursuant to the AFEP-MEDEF Code: Rachel Duan, Lise Kingo, Patrick Kron, Fabienne Lecorvaisier, Melanie Lee, Carole Piwnica, Gilles Schnepp, Diane Souza and Thomas Südhof.

In accordance with the rules described above, Paul Hudson (who is an executive director of Sanofi) and Barbara Lavernos and Christophe Babule (who were appointed on the recommendation of L'Oréal, a major shareholder of Sanofi), are not deemed independent.

Serge Weinberg is no longer deemed independent, pursuant to the AFEP-MEDEF Code, because with effect from December 2021 he has served as a director of Sanofi for more than twelve years.

Consequently, the proportion of independent directors is 69%. This compares with the AFEP-MEDEF recommendation of 50% in companies with dispersed ownership and no controlling shareholder (which is the case for Sanofi). In accordance with the recommendations of the AFEP-MEDEF Code, directors representing employees are excluded when calculating the proportion of independent directors.

	Rachel Duan	Lise Kingo	Patrick Kron	Fabienne Lecorvaisier	Melanie Lee	Carole Piwnica	Gilles Schnepp	Diane Souza	Thomas Südhof
Criterion 1: not an employee/executive officer in past 5 years	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 2: no cross-directorships	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 3: no significant business relationship	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 4: no close family ties	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 5: not an auditor	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 6: not held office for >12 years	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 7: no variable or performance-linked compensation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 8: not a significant shareholder	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Deemed independent	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Failure to fulfil one of the criteria does not automatically disqualify a director from being independent.

In assessing the criterion related to significant business relationships (criterion 3), the Board of Directors took into account the various relationships between directors and Sanofi and concluded that no relationships were of a kind that might undermine their independence. The Board of Directors noted that the Company and its subsidiaries had, in the normal course of business, over the past three years, sold products and provided services to, and/or purchased products and received services from, companies in which certain of the Company's directors who are classified as independent (or their close family members) were senior executives or employees during 2021. In each case, the amounts paid to or received from such companies over the past three years were determined on an arm's length basis and did not represent amounts that the Board regarded as undermining the independence of the directors in question.

Board evaluation

Under the terms of the Board Charter, a discussion of the operating procedures of the Board and its committees must be included on the agenda of one Board meeting every year. The Charter also requires a formal evaluation to be performed at least every three years under the direction of the Appointments, Governance and CSR Committee, with assistance from an independent consultant.

The 2019 and 2020 evaluations were conducted internally, using a detailed questionnaire sent to directors by the Secretary to the Board. Each director was allowed a few weeks to complete the questionnaire using a secure digital platform. At the end of that period, the responses were analyzed by the Secretary to the Board, and supplemented by one-on-one interviews. The results were then presented to, and discussed by, the Appointments, Governance and CSR Committee.

Following the 2020 evaluation (conducted in 2021), the following actions were taken to address the areas for progress and vigilance identified (see our 2020 Annual Report on Form 20-F):

- our Human Resources policy was reviewed and tightened up under the leadership of Sanofi's new Chief People Officer;
- the process of formalizing the succession plan for the Chairman of the Board was agreed; and
- the risk profile and risk management plan was reviewed (with particular reference to the public health crisis triggered by COVID-19), and the Audit Committee reviewed cybersecurity risks in light of stress test results and an analysis of emerging risks (especially in the geopolitical arena).

The remit of the Strategy Committee remained unchanged, with the Appointments, Governance and CSR Committee taking the view that it was consistent with usual practice and served the need of the Board.

In 2021, a formal evaluation was conducted under the direction of the Appointments, Governance and CSR Committee, with the assistance of a specialist consulting firm.

This evaluation took place over several weeks, according to the following procedure:

- issuance of a questionnaire to all directors (the main topics covered by this questionnaire are: alignment of the composition of the Board with Sanofi's needs, quality of support and interventions, working methods, appropriateness of the resources made available to the Board and the Committees, compliance of the company's governance with best practices, quality of debates and freedom of expression, composition and remits of the Committees, relations between the Board and the Executive Committee/shareholders/ stakeholders, expectations of the Directors, personal contributions (competencies, and effective participation in deliberations),
- review of the answers provided by the directors,
- update on the evaluation process at the meeting of the Appointments, Governance and CSR Committee on February 15, 2022,
- individual interviews conducted by a consultant;

The Appointments, Governance and CSR Committee meeting of February 15, 2022 reviewed the results and agreed a summary report including the areas for progress and vigilance identified, which was then presented to the Board on February 22, 2022.

The results of the 2021 evaluation show an improvement in the functioning of the Board since the previous evaluation, the directors having particularly underlined the effectiveness of the Chairman's action and the quality of the dialogue with the Chief Executive Officer.

The following areas for progress have nevertheless been identified;

- the preparation of the Chairman's succession must be continued and accelerated, under the leadership of an independent director;
- the implementation of the CSR strategy will have to be subject to tighter monitoring, which will involve the review by the Appointments, Governance and CSR Committee of the four pillars of the policy from 2022;
- strategic seminars should be more devoted to discussing strategy rather than reviewing activities;
- the duration of the two executive sessions should be extended to allow for more in-depth discussion;
- the integration program for new Directors, made difficult due to the health crisis linked to COVID-19, will have to be reinforced.

Board members stated that COVID had not harmed the working of the Board but they expressed a desire for a rapid return to physical meetings as well as normal social activities.

The Chairman will provide feedback on each Board member's individual performance over the course of the year.

Succession planning

The remit of the Appointments, Governance and CSR Committee includes preparing for the future of the Company’s executive bodies, in particular through the establishment of a succession plan for executive officers.

The plan, which is reviewed at meetings of the Appointments, Governance and CSR Committee, addresses various scenarios:

- unplanned vacancy due to prohibition, resignation or death;
- forced vacancy due to poor performance, mismanagement or misconduct; and
- planned vacancy due to retirement or expiration of term of office.

Through its work and discussions, the Committee seeks to devise a succession plan that is adaptable to situations arising in the short, medium or long term, but which also builds in diversity – in all its facets – as a key factor.

To fulfill its remit, the Appointments, Governance and CSR Committee:

- provides the Board with progress reports, in particular at executive sessions;
- co-ordinates with the Compensation Committee. In that regard, having a director that sits on both Committees is a great advantage;
- works closely with the Chief Executive Officer to (i) ensure the plan is consistent with the Company’s own practices and market practices, (ii) ensure high-potential internal prospects receive appropriate support and training, and (iii) check there is adequate monitoring of key posts likely to fall vacant;
- meets with key executives as needed; and
- involves the Chairman and the Chief Executive Officer insofar as each has a key role in planning for his own successor, though without them directing the process.

In fulfilling their remit, Committee members are acutely conscious of confidentiality issues.

Although aware that separating the offices of Chairman and Chief Executive Officer provides continuity of power, the Committee nonetheless assesses the situation of the Chairman as well as that of the executive team.

Serge Weinberg's current term of office expires at the end of the Annual General Meeting of Sanofi shareholders called to approve the financial statements for the year ended December 31, 2022, and cannot be renewed as he will have reached the age limit stipulated in the Articles of Association (an English language version of which is reproduced in full as Exhibit 1.2 to this Annual Report on Form 20-F). At the instigation of Serge Weinberg and with assistance from a consultancy firm, the Appointments, Governance and CSR Committee has begun preparatory succession planning work, involving consideration of the profile required for the new Chair(woman) and discussions with Board members. That work is being continued and formalized by the Committee during 2022. Gilles Schnepp, who is an independent director and was appointed as Chair of the Committee on December 15, 2021 (following Serge Weinberg's decision to step down as Chair, as mentioned above) will use his governance expertise to support the Committee in this process.

Succession planning for the Chief Executive Officer is subject to regular review by the Appointments, Governance and CSR Committee.

Board Charter

Our Board Charter describes the rights and obligations of Board members; the composition, role and operating procedures of the Board of Directors and Board Committees; and the roles and powers of the Chairman and the Chief Executive Officer. It is prepared in accordance with the French Commercial Code and our Articles of Association.

An English-language version of our Board Charter is reproduced in full as Exhibit 1.2 to this Annual Report on Form 20-F.

Composition of the Board of Directors as of December 31, 2021

As of December 31, 2021, our Board of Directors comprised:

Director	Age	Gender	Nationality	Number of shares	Number of directorships in listed companies[a]	Independent	First appointed	Term expires	Years of Board service	AC	AGC	CC	SC	SciC
Serge Weinberg, Chairman of the Board	71	M	French	1,636	1	No	2009	2023 AGM	12		M		C	M
Paul Hudson, Chief Executive Officer	54	M	British	5,600	1	No	2019	2022 AGM	2				M	
Christophe Babule	56	M	French	1,000	1	No	2019	2022 AGM	2	M				
Rachel Duan	51	F	Chinese	1,000	4	Yes	2020	2024 AGM	1			M		
Lise Kingo	60	F	Danish	1,000	3	Yes	2020	2024 AGM	1		M			
Patrick Kron	68	M	French	1,000	4	Yes	2014	2022 AGM	7		M	C	M	
Wolfgang Laux[b]	54	M	German	3,190	1	No	2021	2025 AGM	0					
Barbara Lavernos	53	F	French/ German	500	1	No	2021	2025 AGM	0					
Fabienne Lecorvaisier	59	F	French	1,000	3	Yes	2013	2025 AGM	8	C				
Melanie Lee	63	F	British	1,000	1	Yes	2017	2025 AGM	4		M			M
Carole Piwnica	64	F	Belgian	1,000	2	Yes	2010	2024 AGM	11			M		
Gilles Schnepp	63	M	French	1,000	4	Yes	2020	2022 AGM	1		C		M	
Diane Souza	69	F	American	1,137	1	Yes	2016	2024 AGM	5	M		M		
Thomas Südhof	66	M	American/ German	1,170	1	Yes	2016	2024 AGM	5					C
Yann Tran[b]	56	M	French	1,066	1	No	2021	2025 AGM	—					

Independent directors [c]	Female directors [c]	Non-French directors
69%	54%	53%

AC: Audit Committee.
AGC: Appointments, Governance and CSR Committee.
CC: Compensation Committee.
SC: Strategy Committee.
SciC: Scientific Committee.
C: Chairman/Chairwoman.
M: Member.
(a) Includes all non-executive and executive (and equivalent) directorships held in listed companies. The office held within Sanofi is included in the calculation of this rate.
(b) Director representing employees.
(c) Directors representing employees are not taken into consideration for the calculation of these percentages.

Competencies of Board members

The Board of Directors, in liaison with the Appointments, Governance and CSR Committee, must ensure that the composition of the Board is balanced, diverse and fit for purpose.

In assessing its composition, the Board takes account of the new challenges facing Sanofi and the corporate strategy, and determines whether the qualities of serving directors are sufficient for the Board to deliver on its remit.

Over the past several years, the Board has adapted its composition in line with its roadmap by:

- bringing additional pharmaceutical industry and healthcare sector expertise onto the Board;
- further raising the proportion of non-French directors, especially those with experience of the Chinese market;
- developing its knowledge of CSR issues; and
- maintaining the level of core competencies, especially in accounting and finance.

The Board has completed an overview of the competencies currently represented. The matrix below[(a)] shows a comprehensive, balanced spread of the types of competencies required, both in general terms and by reference to our strategic ambitions (the matrix shows the number of directors possessing each of those competencies)[(b)]:

Scientific training	3[(c)]
Healthcare/pharmaceutical industry experience	5[(d)]
Senior executive role in international group[(e)]	9[(f)]
Board membership in international group	7[(g)]
International experience[(h)]	9[(i)]
Mergers & acquisitions	8[(j)]
Finance/Accounting	5[(k)]

(a) Based on the composition of the Board as of February 22, 2022.
(b) The information shown excludes directors representing employees.
(c) Barbara Lavernos, Melanie Lee and Thomas Südhof.
(d) Paul Hudson, Rachel Duan, Lise Kingo, Melanie Lee and Diane Souza.
(e) Executive Committee member within an international group.
(f) Serge Weinberg, Paul Hudson, Christophe Babule, Rachel Duan, Lise KIngo, Patrick Kron, Barbara Lavernos, Fabienne Lecorvaisier and Gilles Schnepp.
(g) Serge Weinberg, Rachel Duan, Lise Kingo, Patrick Kron, Fabienne Lecorvaisier, Carole Piwnica and Gilles Schnepp.
(h) Operational role within an international group.
(i) Serge Weinberg, Paul Hudson, Christophe Babule, Rachel Duan, Lise Kingo, Patrick Kron, Fabienne Lecorvaisier, Gilles Schnepp and Diane Souza.
(j) Serge Weinberg, Paul Hudson, Christophe Babule, Patrick Kron, Fabienne Lecorvaisier, Carole Piwnica, Gilles Schnepp and Diane Souza.
(k) Christophe Babule, Fabienne Lecorvaisier, Carole Piwnica, Gilles Schnepp and Diane Souza.

All members of our Board or Directors are engaged with corporate social responsibility issues, for example (non-exhaustive list):

- Serge Weinberg founded Weinberg Capital Partners, a responsible investment fund that takes sustainability criteria into account in its investment decisions and measures the impact of its investments on society and the environment, in 2005;
- Christophe Babule, as CFO of L'Oréal, is in charge of financing the group's sustainable transition. He is also a director of the L'Oréal for Women endowment fund;
- Lise Kingo holds a Master degree in Responsibility & Business Practice from the University of Bath in the United Kingdom. She was Professor of Sustainability and Innovation at the Vrije Universiteit Amsterdam (The Netherlands) from 2006 to 2015, and in parallel held various CSR-related positions including Director of Environmental Affairs at Novozymes and Executive Vice President, Corporate Relations at Novo Nordisk, before becoming CEO & Executive Director of the United Nations Global Compact from 2015 to 2020;
- Patrick Kron, in his capacity as a director of Holcim, is a member of the Health, Safety & Sustainability Committee, a specialist committee of the Holcim board;

- Fabienne Lecorvaisier has experience as Executive Vice President of Air Liquide with responsibiliy for sustainable development, public and international affairs and societal programs, including the Air Liquide Foundation and Inclusive Business;
- Gilles Schnepp led Legrand's CSR policy as Chairman and CEO from 2006 to 2018, and since March 2021 has been Chairman of the Board of Directors of Danone, a *société à mission* (social purpose company). He has also chaired the Ecological and Economic Transition Commission of the MEDEF (the French employer's federation) since 2018.

The terms of office of Paul Hudson, Christophe Babule, Patrick Kron and Gilles Schnepp will expire at the General Meeting to be held on May 3, 2022. In addition, Melanie Lee and Carole Piwnica will leave the Board of Directors ahead of the General Meeting. The General Meeting of Sanofi shareholders of May 3, 2022 will be asked to approve:

- the renewal of the terms of office of:
  - Paul Hudson, who has served as our Chief Executive Officer since September 1, 2019 and was appointed as a director in October 2019, succeeding Olivier Brandicourt who had served as Chief Executive Officer until August 31, 2019. Renewing Paul Hudson's term of office will enable to play a full part in the work of the Board, and to contribute his in-depth knowledge of the pharmacetical industry,
  - Christophe Babule (refer to his career résumé on page 86, and his competencies as shown in the table above),
  - Patrick Kron (refer to his career résumé on page 89, and his competencies as shown in the table above),
  - Gilles Schnepp (refer to his career résumé on page 95, and his competencies as shown in the table above); and
- the appointment as a new director of:
  - Carole Ferrand: Finance/accounting, Board membership in international groups;
  - Emile Voest: Scientific training;
  - Antoine Yver: Scientific training, International experience, Healthcare / Pharmaceutical industry experience.

The following pages provide key information about each director individually:

- directorships and appointments held during 2021 (directorships in listed companies are indicated by an asterisk, and each director’s principal position is indicated in bold);
- other directorships held during the last five years;
- training and professional experience; and
- competencies.

Serge Weinberg

Date of birth: February 10, 1951 (aged 71)
Nationality: French
First appointed: December 2009
Last reappointment: April 2019
Term expires: 2023
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 1,636 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Director and Chairman of the Board of Directors

- Chairman of the Strategy Committee
- Member of the Appointments, Governance and CSR Committee
- Member of the Scientific Committee

OUTSIDE THE SANOFI GROUP

In French companies

Chairman of Weinberg Capital Partners:
- Chairman of Maremma
- Manager of Alret

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- Permanent representative of Weinberg Capital Partners on the Board of Directors of ADIT (ended October 4, 2019)
- Director of Madrigall (ended June 19, 2019)
- Chairman of the Supervisory Boards of Financière Climater SAS (ended October 31, 2018) and Financière Tess SAS (ended October 4, 2019)
- Chairman of Financière Piasa and Piasa Holding (ended October 5, 2018)

In foreign companies

- Chairman of Corum (Switzerland)

Education and professional experience

- Graduate in law, degree from the *Institut d'Études Politiques*
- Graduate of ENA (*École Nationale d'Administration*)

Since 2005	**Chairman of Weinberg Capital Partners**
2005-2010	Vice Chairman of the Supervisory Board of Schneider Electric*
2006-2009	Chairman of the Board of Accor*
1990-2005	Various positions at PPR* group including Chairman of the Management Board for 10 years
1987-1990	Chief Executive Officer of Pallas Finance
1982-1987	Deputy General Manager of FR3 (French television channel) and then Chief Executive Officer of Havas Tourisme
1976-1982	*Sous-préfet* and then Chief of Staff of the French Budget Minister (1981)

Competencies

Senior executive in international group, Board membership in international group, International experience, Mergers & acquisitions

Paul Hudson

Date of birth: October 14, 1967 (aged 54)
Nationality: British
First appointed: September 2019
Term expires: 2022
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 5,600 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Chief Executive Officer

- Chairman of the Executive Committee
- Director
- Member of the Strategy Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Education and professional experience

- Degree in economics from Manchester Metropolitan University, UK
- Diploma in marketing from the Chartered Institute of Marketing, UK
- Honorary Doctorate in Business Administration, Manchester Metropolitan University, UK

From September 1, 2019	**Chief Executive Officer of Sanofi***
2016-2019	CEO of Novartis Pharmaceuticals, member of Executive Committee
2006-2016	Various operational and managerial positions at AstraZeneca (including President, AstraZeneca US; Executive Vice President, North America; Representative Director & President, AstraZeneca KK, Japan; President of AstraZeneca Spain; and Vice-President and head of Primary Care United Kingdom)
Before 2006	Various operational and managerial positions at Schering-Plough, including Head of Global Marketing for biologicals. Various sales and marketing positions at GlaxoSmithKline UK and Sanofi-Synthélabo UK

Competencies

Healthcare/pharmaceutical industry experience, Senior executive role in international group, International experience, Mergers & acquisitions

Christophe Babule

Date of birth: September 20, 1965 (aged 56)
Nationality: French
First appointed: February 2019
Term expires: 2022
Business address: Sanofi - 54, rue La Boétie - 75008 Paris, France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Director

- Member of the Audit Committee

OUTSIDE THE SANOFI GROUP

In French companies

Director of the "L'Oréal Fund for Women" charitable endowment fund

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

L'Oréal* Group:

- Director of L'Oréal USA Inc. (United States)

Education and professional experience

- Education and professional experience

Since February 2019	**Chief Financial Officer at L'Oréal***
Since 1988	Various positions within the L'Oréal* Group, including as Director of Administration & Finance for China, then Mexico; Director of Internal Audit; and Administration & Financial Director for the Asia Pacific Zone

Competencies

Senior executive role in international group, International experience, Mergers & acquisitions, Finance/Accounting

Rachel Duan

Date of birth: July 25, 1970 (aged 51)
Nationality: Chinese
First appointed: April 2020
Term expires: 2024
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Compensation Committee

OUTSIDE THE SANOFI GROUP

In French companies

Independent director of AXA*

In foreign companies

Independent director of HSBC*

Independent director of Adecco Group*

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Education and professional experience

- MBA, University of Wisconsin-Madison (United States)
- Bachelor's degree in Economics and International Trade, Shanghai International Studies University (China)

1996-2020	Senior Vice President of General Electric* (United States) and President & CEO of GE Global Markets (China) Various leadership positions within the GE group, including President & CEO of GE Advanced Materials China and then Asia Pacific, President & CEO of GE Healthcare China, and President & CEO of GE China.

Competencies

Healthcare/pharmaceutical industry experience, Senior executive role in international group, Board membership in international group, International experience

Lise Kingo

Date of birth: August 3, 1961 (aged 60)
Nationality: Danish
First appointed: April 2020
Term expires: 2024
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Appointments, Governance & CSR Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- Independent director of Covestro AG* (Germany)
- Independent director of Aker Horizons ASA* (Norway)

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Education and professional experience

- Bachelor's degree in Religions and Ancient Greek Art, University of Aarhus (Denmark)
- Bachelor's degree in Marketing and Economics, Copenhagen Business School (Denmark)
- Master's degree in Responsibility & Business, University of Bath (United Kingdom)
- Director Certification, INSEAD (France)

2021	Independent Director, Covestro AG* (Germany)
2021	Independent Director, Aker Horizons ASA* (Norway)
2020	Member of the Advisory Panel for Humanitarian and Development Coordination, Novo Nordisk Foundation (Denmark)
2020	Chair of Blueprint for Denmark Initiative (Denmark)
2015-2020	Director of Principles for Responsible Investment, UN PRI (UK)
2015-2020	CEO & Executive Director of United Nations Global Compact (USA)
2014-2015	Deputy chair of the Danish Foundation for Nature Preservation (Denmark)
2013-2015	Member of the "Scale for Good" Advisory Panel, Tesco Plc, (United Kingdom)
2012-2015	Chair of the Danish Council for Corporate Social Responsibility (Denmark)
2012-2015	Independent Director of Grieg Star Shipping (Norway)
2010-2014	Chair, Steno Diabetes Center (Denmark)
2006-2015	Professor of Sustainable Development and Innovation at Vrije Universiteit Amsterdam (Netherlands)
2005-2009	Independent Director and Deputy Chairwoman, GN Store Nord (Denmark)
2002-2014	Executive Vice President Corporate Relations & Chief of Staff at Novo Nordisk A/S (Denmark)
1999-2002	Senior Vice President, Stakeholder Relations at Novo Holding (Denmark)
1995-2006	Member of the HRH Prince of Wales Cambridge University Faculty for Sustainability Leadership (United Kingdom)
1988-1999	Various positions at the Bioindustrial Novo Industry group, now Novozymes (Denmark), including Promotion Coordinator and Director, Corporate Environmental Affairs.

Competencies

Healthcare/pharmaceutical industry experience, Senior executive role in international group, Board membership in international group, International experience

Patrick Kron

Date of birth: September 26, 1953 (aged 68)
Nationality: French
First appointed: May 2014
Last reappointment: May 2018
Term expires: 2022
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Chairman of the Compensation Committee
- Member of the Appointments, Governance and CSR Committee
- Member of the Strategy Committee

OUTSIDE THE SANOFI GROUP

In French companies

Chairman of Imerys*
Chairman of Truffle Capital SAS
Chairman of PKC&I SAS:
- Permanent representative of PKC&I on the Supervisory Board of Segula Technologies

In foreign companies

Director of Holcim* (Switzerland)
Director of Viohalco* (Belgium)

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

Interim Chief executive Officer of Imerys*
Director of Bouygues*

In foreign companies

ElvalHalcor* (Greece)

Education and professional experience

- Degree from *École Polytechnique* and *École Nationale Supérieure des Mines de Paris*

Since 2019	**Chairman of Imerys*** (and Interim Chief Executive Officer from October 2019 to February 2020)
Since 2016	Chairman of Truffle Capital SAS
Since 2016	Chairman of PKC&I SAS
2003-2016	Chief Executive Officer, then Chairman and Chief Executive Officer, of Alstom*
1998-2002	Chairman of the Managing Board of Imerys
1995-1997	Manager of the Food and Health Care Packaging Sector at Pechiney, and Chief Operating Officer of American National Can Company in Chicago (United States)
1993-1997	Chairman and Chief Executive Officer of Carbone Lorraine
1993	Member of the Executive Committee of the Pechiney Group
1988-1993	Various senior operational and financial positions within the Pechiney Group
1984-1988	Operational responsibilities in one of the Pechiney Group's biggest factories in Greece, then manager of the Greek subsidiary of Pechiney
1979-1984	Various positions at the French Ministry of Industry, including as project officer at the *Direction régionale de l'Industrie, de la Recherche et de l'Environnement* (DRIRE) and in the Ministry's general directorate

Competencies

Senior executive role in international group, Board membership in international group, International experience, Mergers & acquisitions

Wolfgang Laux

Date of birth: January 24, 1968 (aged 54)
Nationality: German
First appointed: April 2021
Term expires: 2025
Business address: Sanofi - 54, rue La Boétie - 75008 Paris
Number of shares held: 3,190 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Director representing the employees

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Education and professional experience

- Post-doctoral research fellow at the State University of New York at Stony Brook (1998-2000) and at the University of Montpellier (1996-1997)
- Ph.D. in organic chemistry from the University of Frankfurt am Main

Since 2006	**Industrialization Coordinator at Sanofi Chimie headquarters, Croix-de-Berny and Gentilly (France)**
Since 2014	Staff representative on the CFE-CGC ticket
2016-2021	Union delegate
2014-2021	Member of the Works Council, Sanofi Chimie headquarters
2016-2019	Member of the Committee on health, safety and working conditions (CHSCT)
2000-2006	Senior scientist in Process Development at the Frankfurt site of Höchst AG

Competencies

Scientific training, Healthcare/pharmaceutical industry experience, International experience.

Barbara Lavernos

Date of birth: April 22, 1968 (aged 53)
Nationality: French and German
First appointed: April 2021
Term expires: 2025
Business address: Sanofi - 54, rue La Boétie - 75008 Paris
Number of shares held: 500 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Director

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- Director of Bpifrance Investment and Bpifrance Participations

In foreign companies

- None

Education and professional experience

- Graduate of the HEI chemical engineering school at Lille (HEI France)

Since May 2021	**Deputy CEO of L'Oréal* in charge of Research, Innovation and Technology**
February 2021	President Research, Innovation and Technologies at L'Oréal*– Member of the Executive Committee at L'Oréal*
2018-2021	Chief Technology and Operations Officer at L'Oréal* – Member of the Executive Committee at L'Oréal*
2014-2018	Executive Vice-President Operations at L'Oréal* – Member of the Executive Committee at L'Oréal*
2011-2014	Managing Director of Travel Retail at L'Oréal*
2004-2011	Global Chief Procurement Officer at L'Oréal*

Competencies

Senior executive role in international group, Scientific training

Fabienne Lecorvaisier

Date of birth: August 27, 1962 (aged 59)
Nationality: French
First appointed: May 2013
Last reappointment: April 2021
Term expires: 2025
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Chair of the Audit Committee

OUTSIDE THE SANOFI GROUP

In French companies

Air Liquide Group*:
- Director of Air Liquide International
- Chairwoman of Air Liquide Finance
- Director of The Hydrogen Company

Safran Group*:
- Independent Director
- Member of the Audit and Risk Committee

In foreign companies

Air Liquide Group*:
- Executive Vice President of Air Liquide International Corporation
- Director of American Air Liquide Holdings, Inc.

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

Air Liquide Group*:
- Director of Air Liquide Eastern Europe, Air Liquide France Industries, Aqualung International, Air Liquide Welding SA and SOAEO
- Director of ANSA (Association Nationale des Sociétés par Actions)

In foreign companies

- Chairwoman of Air Liquide US LLC

Education and professional experience

- Civil engineer, graduate of *École Nationale des Ponts et Chaussées*

Since July 2021	**Executive Vice President in charge of Sustainable Development, Public and International Affairs, Social Programs and General Secretariat of Air Liquide***
July 2017-July 2021	Executive Vice President of Air Liquide*
Since 2008	Executive Committee member of Air Liquide*
2008-2021	Chief Financial Officer of Air Liquide*
1993-2008	Various positions within Essilor* including Group Chief Financial Officer (2001-2007) and Chief Strategy and Acquisitions Officer (2007-2008)
1990-1993	Assistant General Manager of Banque du Louvre, Taittinger Group
1989-1990	Senior Banking Executive in charge of the LBO Department (Paris)/Corporate Finance Department (Paris and London) at Barclays
1985-1989	Member of the Corporate Finance Department, then Mergers and Acquisitions Department of Société Générale*

Competencies

Senior executive role in international group, Board membership in international group, International experience, Mergers & acquisitions, Finance/Accounting

Melanie Lee

Date of birth: July 29, 1958 (aged 63)
Nationality: British
First appointed: May 2017
Last reappointment: April 2021
Term expires: 2025
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Scientific Committee
- Member of the Appointments, Governance and CSR Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

CEO of independent Medical Charity, LifeArc
Director of Think10 (United Kingdom)

Director of Lee Smith Properties Ltd (United Kingdom)

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

Director of Syntaxin Ltd.* (United Kingdom)
Director of BTG plc.* (United Kingdom)
Non-executive director of Lundbeck A/S (Denmark)
Director of NightstaRx Ltd. (United Kingdom)
Executive Director of Celltech plc

Education and professional experience

- Degree in Biology, University of York
- Ph.D. from the National Institute for Medical Research, London
- Commander of the Order of the British Empire award in 2009 for services to medical science

Since 2018	**Chief Executive Officer of LifeArc (United Kingdom)**
2019	Bio Industry Association (BIA) lifetime achievement award
Since 2013	Director and Consultant, Think10 (United Kingdom)
2014-2018	Chief Scientific Officer of BTG plc* (United Kingdom)
2011-2015	Non-executive director of Lundbeck A/S (Denmark)
2014	Named as one of the 'leading practical scientists' in the UK by the Science Council
2014	Founder of NightstaRx Ltd. (United Kingdom)
2009-2013	Chief Executive Officer and Director of Syntaxin Ltd.* (United Kingdom)
2003-2011	Deputy Chairwoman of Cancer Research U.K. (United Kingdom)
1998-2009	Executive Director of Research at Celltech plc., and subsequently Executive Vice President, Research and President New Medicines at UCB Celltech (United Kingdom)
1988-1998	Senior Biologist and subsequently Research Unit Head, Receptor Systems at Glaxo/GlaxoWellcome (United Kingdom)

Competencies

Scientific training, Healthcare/pharmaceutical industry experience

Carole Piwnica

Date of birth: February 12, 1958 (aged 64)
Nationality: Belgian
First appointed: December 2010
Last reappointment: April 2020
Term expires: 2024
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Compensation Committee

OUTSIDE THE SANOFI GROUP

In French companies

Rothschild & Co*:
- Independent member of the Supervisory Board and of the Remuneration & Nomination Committee

In foreign companies

Managing Partner of Naxos S.A. (Switzerland)

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

Eutelsat Communications*:
- Independent director
- Chairwoman of the Nomination and Governance Committee

In foreign companies

Director of Louis Delhaize* (Belgium), RecyCoal Ltd. (United Kingdom) and Big Red (United States)
Director of Naxos UK Ltd (United Kingdom)
Director of Elevance (United States) and i2O (United Kingdom)

Director of Amyris Inc* (United States)

Education and professional experience

- Degree in law, Université Libre de Bruxelles
- Master of Laws, New York University
- Admitted to the Bar in Paris and New York

Since 2018	**Managing Partner of Naxos S.A. (Switzerland)**
2007- 2018	Founder Director of Naxos UK Ltd (United Kingdom)
2003-2011	Director, Chairwoman of the Corporate Responsibility Committee and member of the Compensation Committee of Aviva Plc* (United Kingdom)
2007-2010	Director of Dairy Crest Plc* (United Kingdom)
1996-2010	Director of Toepfer GmbH (Germany)
2006-2009	Member of the Ethical Committee of Monsanto* (United States)
2000-2006	Chairwoman of the Export Commission and director of the *Association Nationale des Industries Alimentaires* (ANIA)
2000-2006	Director and Vice-Chairwoman of Tate & Lyle Plc for Governmental Affairs (United Kingdom)
1996-2006	Chairwoman of the Liaison Committee and director of the *Confédération Européenne des Industries Agro-Alimentaires* (CIAA)
1996-2006	Director of Tate & Lyle Plc (United Kingdom)
1998-2004	Director of Spadel (Belgium)
1994-2000	Chief Executive Officer of Amylum France, then Chairwoman of Amylum Group
1991-1994	General Counsel of Gardini & Associés
1985-1991	Attorney at Proskauer, Rose (New York) and Shearman & Sterling (Paris) with practice in mergers and acquisitions

Competencies

Board membership in international group, Mergers & acquisitions, Finance/Accounting

Gilles Schnepp

Date of birth: October 16, 1958 (aged 63)
Nationality: French
First appointed: May 2020
Term expires: 2022
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 1,000 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Chairman of the Appointments, Governance and CSR Committee
- Member of the Strategy Committee

OUTSIDE THE SANOFI GROUP

In French companies

Member of the Board of Directors of Legrand*
Member of the Board of Directors of Saint Gobain*
Chairman of the Board of Directors of Danone*

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

Vice-Chairman of the Supervisory Board of PSA*

In foreign companies

- None

Education and professional experience

- Graduate of HEC business school

Since 2021	**Chairman of Danone***
Since 2020	Member of the Board of Directors of Legrand
Since 2009	Member of the Board of Directors of Saint Gobain
2019-2021	Vice-Chairman of the Supervisory Board of PSA
2006-2018	Chairman & CEO of Legrand
2004-2006	CEO of Legrand
2001-2004	Deputy CEO of Legrand
1989-2001	Various positions within the Legrand group
1983	Merrill Lynch

Competencies

Senior executive role in international group, Board membership in international group, International experience, Mergers & acquisitions, Finance/Accounting

Diane Souza

Date of birth: July 3, 1952 (aged 69)
Nationality: American
First appointed: May 2016
Last reappointment: April 2020
Term expires: 2024
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 2,343 American Depositary Receipts, equivalent to 1,172 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Member of the Compensation Committee
- Member of the Audit Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

Amica Insurance Companies (United States):
- Member of the Board of Directors
- Member of the Compensation and Investment Committees

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

UnitedHealth Group:
- Member of the Board of Directors of Unimerica Insurance Company, Unimerica Life Insurance Company of New York, National Pacific Dental, Inc., Nevada Pacific Dental, DBP Services of New York, IPA, Dental Benefits Providers of California, Inc., Dental Benefit Providers of Illinois, Inc., Dental Benefit Providers, Inc., Spectera, Inc. and Spectera of New York, IPA, Inc. United States

Farm Credit East (United States)
- Member of the Board of Directors

Education and professional experience

- Degree in Accounting from University of Massachusetts
- Honorary doctorate in Business Administration from University of Massachusetts Dartmouth
- Certified Public Accountant
- Diploma in Dental Hygiene from Northeastern University, Forsyth School for Dental Hygienists

2008-2014	Chief Operating Officer of OptumHealth Specialty Benefits (2008), then Chief Executive Officer of UnitedHealthcare Specialty Benefits (2009-2014) (United States)
2007-2008	Principal consultant at Strategic Business Solutions, LLC (United States)
1994-2006	Various positions at Aetna Inc. including Deputy Vice President Federal and State Taxes; Vice President and Chief Financial Officer, Large Case Pensions; Vice President and Head of Global Internal Audit Services; Vice President, National Customer Operations; and finally Vice President, Strategic Systems & Processes (United States)
1988-1994	Various positions at Price Waterhouse from Audit Staff Accountant to Head of the Northeast Insurance Tax Region (United States)
1980-1988	Various positions at Deloitte Haskins & Sells, from Audit Staff Accountant to Senior Tax Manager-in-Charge (United States)
1979	Audit Staff Accountant at Price Waterhouse (United States)

Competencies

Healthcare/pharmaceutical industry experience, International experience, Mergers & acquisitions, Finance/Accounting

Thomas Südhof

Date of birth: December 22, 1955 (aged 66)
Nationality: German and American
First appointed: May 2016
Last reappointment: April 2020
Term expires: 2024
Business address: Sanofi - 54, rue La Boétie - 75008 Paris - France
Number of shares held: 2,340 American Depositary Receipts, equivalent to 1,170 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Independent director

- Chairman of the Scientific Committee

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

Independent director of CytoDel Inc. (United States) (since 2021)

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- None

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

Independent director of Abide Therapeutics (United States) (2019-2020)

Education and professional experience

- Degree in medicine from the Faculty of Medicine of the University of Göttingen (Germany)
- Elected member of the National Academy of Sciences of the USA (2002)
- Elected member of the National Academy of Medicine (2007)
- Bernard Katz Prize of the Biophysical Society, jointly with Reinhard Jahn (2008)
- Elected member of the American Academy of Arts and Sciences (2010)
- Nobel Prize for Physiology or Medicine, jointly with James Rothman and Randy Schekman (2013)
- Albert Lasker Prize for Basic Medical Research, jointly with Richard Scheller (2013)
- Elected foreign member of the German Academy Leopoldina (2015)
- Elected foreign member of the Royal Society of London for Improving Natural Knowledge (2017)
- Elected member of the Norwegian Society of Sciences

Since 2008	**Avram Goldstein Professor in the Molecular & Cellular Physiology, Neurosurgery, Psychiatry, and Neurology Department in the School of Medicine at Stanford University (United States)**
Since 2020	Member of the Scientific Advisory Board of Danaher Corporation (United States)
Since 2020	Co-founder and member of the Scientific Advisory Board of Boost, Inc. and Recognify, Inc. (United States)
Since 2020	Member of the Scientific Advisory Board of NeuroCure, Charite, Berlin (Germany)
Since 2019	Member of the Scientific Advisory Board of the Neuroscience Department at the Institut Pasteur (France)
Since 2019	Member of the Scientific Advisory Board of the Chinese Institute for Brain Research, Beijing (China)
Since 2019	Advisor to Camden Venture Partners (United States)
Since 2018	Member of the Scientific Advisory Board of Jupiter, Inc. (United States)
Since 2018	Chairman of the Scientific Advisory Board of Capital Medical University, Beijing (China)
Since 2018	Member of the Scientific Advisory Board of Alector, Inc. (United States)
Since 2017	Member of the Scientific Advisory Board of Cytodel, Inc. (United States)
Since 2017	Member of the Scientific Advisory Board of the Chinese Academy of Sciences Institute of Guangzhou (China)
Since 2016	Member of the Scientific Advisory Board of the Picower Institute, MIT Boston (United States)
Since 2016	Member of the Scientific Advisory Board of Simcere, Inc. (China)
Since 2014	Member of the Scientific Advisory Board of Elysium, Inc. (United States)
Since 2013	Member of the Scientific Advisory Board of the Shemyakin-Ovchinnikov Institute of Bio-Organic Chemistry (Russia)
Since 2002	Co-founder and member of the Scientific Advisory Board of REATA Pharmaceuticals (United States)
Since 1986	Investigator at the Howard Hughes Medical Institute (United States)
2017-2019	Member of the Scientific Advisory Board of C-Bridge Everest Medical (China)
2017-2018	Member of the Scientific Advisory Board of Abide (United States)
2014-2018	Member of the Scientific Advisory Committee of the Institute of Cellular and Molecular Biology of A*Star (China)
2014-2018	Member of the Scientific Advisory Board of the Chinese Academy Institute of Biophysics (China)

2014-2018	Member of the Scientific Advisory Board of the Singapore National Research Foundation (Singapore)
2014-2017	Co-founder and member of the Scientific Advisory Board of Bluenobel, Inc. (China)
2013-2016	Member of the Review Board of Genentech Neuroscience (United States)
2011-2019	Co-founder and member of the Scientific Advisory Board of Circuit Therapeutics, Inc. (United States)
1986-2008	Professor and subsequently Chair of the Neuroscience Department at the University of Texas Southwestern Medical School (United States)
1983-1986	Postdoctoral Fellow, Dept. of Molecular Genetics, UT Southwestern Medical School (United States)
1981-1982	Intern at the University Hospital of Göttingen (Germany)
1979	Student on exchange clerkship program at Harvard Medical School (United States)
1978-1981	Research assistant at the Max Planck Institute for Biophysical Chemistry (Germany)

Competencies
Scientific training

Yann Tran

Date of birth: December 5, 1965 (aged 56)
Nationality: French
First appointed: May 2021
Term expires: 2025
Business address: Sanofi - 54, rue La Boétie - 75008 Paris
Number of shares held: 1,066 shares

Current directorships and appointments

WITHIN THE SANOFI GROUP

Director representing the employees

OUTSIDE THE SANOFI GROUP

In French companies

- None

In foreign companies

- None

Past directorships expiring within the last five years

WITHIN THE SANOFI GROUP

- Coordinator for IndustriALL Europe on the Sanofi European Works

OUTSIDE THE SANOFI GROUP

In French companies

- Member of the French Strategy Committee for the Healthcare Industries and Technologies Sector

In foreign companies

- None

Education and professional experience

- DEA in Biochemistry: Integrative Protein Biology from the University of Paris VII (France)
- Master's degree in Biochemical and Biological Engineering Sciences and Techniques from the University of Paris XII (France)

Since 2010	**Head of Labor Relations, France at Sanofi**
2021	Coordinator for IndustriALL Europe on the Sanof European Works Council
2014-2021	Federation delegate for the Pharmaceuticals industry, in charge of negotiating and monitoring of industry agreements and national collective agreements
2014-2021	FCE-CFDT federation delegate for social welfare
2010-2021	Trade union leader in labor relations in the Sanofi group
2010-2014	Member of the Supervisory Board of Sanofi employee savings plans (PEG and PERCO) and member of the Sanofi Group Committee
2006-2010	Bioinformatics researcher at Sanofi R&D
1995-2006	Researcher in molecular biology at Sanofi and Aventis

Competencies

Scientific training, Healthcare/pharmaceutical industry experience

Changes in the composition of the Board of Directors

The table below shows changes in the composition of the Board of Directors during 2020 and 2021, and the changes that will be submitted for approval by our shareholders at the Annual General Meeting of May 3, 2022:

	Annual General Meeting of April 28, 2020	Annual General Meeting of April 30, 2021	Annual General Meeting of May 3 2022
End of term of office	Claudie Haigneré[a] Suet-Fern Lee[b]	Marion Palme[d] Christian Senectaire[d] Laurent Attal[e] Bernard Charlès[f]	Melanie Lee [g] Carole Piwnica [g]
Renewal of term of office	Laurent Attal Carole Piwnica Diane Souza Thomas Südhof	Fabienne Lecorvaisier Melanie Lee	Paul Hudson Christophe Babule Patrick Kron Gilles Schnepp
Proposed new appointments	Rachel Duan (independent director) Lise Kingo (independent director)	Barbara Lavernos[e]	Carole Ferrand [g] Emile Voest [g] Antoine Yver [g]
Co-opted	Paul Hudson[c]	Gilles Schnepp	None
Other	None	Wolfgang Laux[d] Yann Tran[d]	None

(a) Claudie Haignéré's term of office expired at the end of the Annual General Meeting of April 28, 2020; she was not proposed for reappointment because she had already served as a director of Sanofi for 12 years.

(b) Suet-Fern Lee resigned as a director effective as of the General Meeting of April 28, 2020.

(c) Paul Hudson was co-opted by the Board of Directors on October 30, 2019 following the resignation of Olivier Brandicourt as a director.

(d) The terms of office of Marion Palme and Christian Senectaire, directors representing employees, expired at the end of the Annual General Meeting of April 30, 2021. In accordance with Article 11 of our Articles of Association, the trade union body which is the most representative (within the meaning of the applicable legislation) within the Company and those of its direct or indirect subsidiaries that have their registered office in French territory has appointed Yann Tran as director representing employees, and the European Works Council has appointed Wolfgang Laux as the second director representing employees. The terms of office of Yann Tran and Wolfgang Laux will expire at the end of the General Meeting called in 2025 to approve the financial statements for the year ending December 31, 2024.

(e) Laurent Attal resigned as a director effective as of the Annual General Meeting of April 30, 2021.

(f) Bernard Charlès, whose term of office expired at the end of the Annual General Meeting held on April 30, 2021, did not wish to have his term of office renewed. The Board of Directors meeting of April 3, 2021 proposed the appointment of Christian Brandts to replace Bernard Charlès. While the University Cancer Center Frankfurt had initially consented to the appointment of Christian Brandts as a director of Sanofi, and that appointment was announced by way of a press release, Sanofi was subsequently notified that such consent had been withdrawn.

(g) Melanie Lee and Carole Piwnica will leave the Board of Directors ahead of the General Meeting of May 3, 2022.

On December 15, 2021 the Board of Directors appointed Gilles Schnepp, an independent director, as Chairman of the Appointments, Governance and CSR Committee. As of the same date, Gilles Schnepp resigned as a member of the Audit Committee. This appointment follows Serge Weinberg's decision to step down as Chairman of the Appointments, Governance and CSR Committee, as having reached twelve years of service on the Board of Directors of Sanofi in December 2021 he is no longer deemed an independent director under the terms of the AFEP-MEDEF Code as applied by Sanofi.

If the terms of office of Paul Hudson, Christophe Babule, Patrick Kron and Gilles Schnepp were to be renewed, and the appointments of Carole Ferrand, Emile Voest and Antoine Yver approved, the number of Board members would increase to sixteen(fifteen); the proportion of independent directors would be increased from 69% to 71%; the proportion of female directors would be reduced from 54% to 43%; and the proportion of non-French directors would be reduced from 53% to 43%.

As of December 31, 2021, the members of our Board of Directors collectively held (directly, or via the employee share ownership fund associated with the Group savings scheme) 22,334 of our shares, representing 0.0017% of our share capital.

As of December 31, 2021, no corporate officer has been the subject of any conviction or court order, or been associated with any bankruptcy or winding-up order. As of this day, there is no potential conflict of interest between any corporate officer and Sanofi.

Under current French legislation, and given that employees own less than 3% of our share capital, the Board does not include a director representing employee shareholders.

Executive Committee

The Executive Committee is chaired by the Chief Executive Officer. The Committee meets at least twice a month.

There were changes in the composition of the Executive Committee during 2021, with two members (Karen Linehan and Philippe Luscan) leaving and one new member (Brendan O'Callaghan) joining. Roy Papatheodorou joined the Executive Committee on February 1, 2022.

As of February 23, 2022, the Executive Committee had 11 members, two of whom are women. In accordance with our Board Charter (as amended on July 28, 2021), the Board of Directors – in liaison with the Compensation Committee and the Appointments, Governance and CSR Committee, and on a proposal from the Chief Executive Officer – has established a policy on gender balance within Sanofi's executive bodies.

Paul Hudson

Chief Executive Officer

Date of birth: October 14, 1967.

Paul Hudson joined Sanofi as Chief Executive Officer on September 1, 2019.

Previously CEO of Novartis Pharmaceuticals (2016-2019), where he was a member of the Executive Committee, Paul has had an extensive international career in healthcare that spans the US, Japan and Europe.

Prior to Novartis, he worked for AstraZeneca, where he held several increasingly senior positions and most recently carried out the roles of President, AstraZeneca United States and Executive Vice President, North America.

He began his career in sales and marketing roles at GlaxoSmithKline UK and Sanofi-Synthélabo UK.

Paul holds a degree in economics from Manchester Metropolitan University in the UK and last year his alma mater awarded him an honorary Doctor of Business Administration for his achievements in industry. He also holds a diploma in marketing from the Chartered Institute of Marketing, also in the UK.

Paul Hudson is a citizen of the United Kingdom.

Natalie Bickford

Executive Vice President, Chief People Officer

Date of birth: July 16, 1970.

Natalie Bickford joined Sanofi on August 1, 2020.

She holds a degree in French and International Politics from the University of Warwick in the UK.

She has worked in HR and HR leadership for more than 20 years and brings a wealth of experience in consumer-facing industries to Sanofi.

Prior to joining Sanofi, Natalie was Group HR Director at Merlin Entertainments, the world's second largest location-based entertainment business, where she was responsible for 30,000 employees across Europe, North America, and Asia Pacific. She also held senior HR positions at Sodexo, AstraZeneca and Kingfisher Plc.

Natalie has a solid track record of transforming organizations, with a strong focus on inclusion and diversity. She was awarded "HR Diversity Champion of the Year" at the European Diversity Awards in November 2019. Natalie is also Board member of the Kronos Workforce Institute, a reflection of her deep interest in understanding and shaping the future of work.

Natalie Bickford is a citizen of the United Kingdom.

Olivier Charmeil

Executive Vice President, General Medicines

Date of birth: February 19, 1963.

Olivier Charmeil is a graduate of HEC (*Ecole des Hautes Etudes Commerciales*) and of the *Institut d'Etudes Politiques* in Paris. From 1989 to 1994, he worked in the Mergers & Acquisitions department of Banque de l'Union Européenne. He joined Sanofi Pharma in 1994 as head of Business Development. Subsequently, he held various positions within Sanofi, including Chief Financial Officer (Asia) of Sanofi-Synthélabo in 1999 and Attaché to the Chairman, Jean-François Dehecq, in 2000, before being appointed as Vice President, Development within the Sanofi-Synthélabo International Operations Directorate, where he was responsible for China and support functions. In 2003, Olivier Charmeil was appointed Chairman and Chief Executive Officer of Sanofi-Synthélabo France, before taking the position of Senior Vice President, Business Management and Support within the Pharmaceutical Operations Directorate. In this role, he piloted the operational integration of Sanofi-Synthélabo and Aventis. He was appointed Senior Vice President Asia/Pacific, Pharmaceutical Operations in February 2006; Operations Japan reported to him from January 1, 2008, as did Asia/Pacific and Japan Vaccines from February 2009. On January 1, 2011, Olivier Charmeil was appointed Executive Vice President Vaccines, and joined our Executive Committee.

In May 2015, Olivier Charmeil and André Syrota were appointed as Co-Leaders of "Medicine of the Future", an initiative developed by the French Minister for Economy, Industry and Digital Affairs, the French Minister for Social Affairs, Health and Women's Rights and the French Minister for National and Higher Education and Research. They have been tasked with assembling a group of industrialists and academics, with the objective of imagining how French industry can accelerate the launch and export of innovative industrial products, with an emphasis on new biotechnologies.

From June 2016 to December 2018, Olivier Charmeil served as Executive Vice President of our General Medicines and Emerging Markets Global Business Unit.

He took up the position of Executive Vice President China & Emerging Markets in January 2019. In February 2020 he was appointed to lead the General Medicines GBU, created out of the former Primary Care and China & Emerging Markets GBUs. He also serves as sponsor for China. Also in 2020, Olivier became a Board Member of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Olivier Charmeil is a citizen of France.

Jean-Baptiste Chasseloup de Chatillon

Executive Vice President, Chief Financial Officer

Date of birth: March 19, 1965.

Jean-Baptiste Chasseloup de Chatillon joined Sanofi on October 1, 2018.

Jean-Baptiste Chasseloup de Chatillon holds a Masters from Paris Dauphine University and studied Finance in the United Kingdom at Lancaster University.

Until July 2018, he served as Chief Financial Officer and Executive Vice President of the PSA Group. In that capacity, he was also a member of the Managing Board and Executive Committee. He held various management positions within the PSA Group in finance (Treasurer in Spain, Chief Financial Officer in the United Kingdom) and in sales and marketing (Business units: Bank/Insurance, Spare parts, Used vehicles, Proprietary dealership network).

He was also Chairman of the Board of Banque PSA Finance (BPF) from 2012 to June 2016. He joined the Peugeot S.A. Managing Board in 2012.

He was appointed as Director and member of the Audit Committee of Sodexo (a French listed company) on December 14, 2021.

Jean-Baptiste Chasseloup de Chatillon is a citizen of France.

Brendan O'Callaghan

Executive Vice President, Global Industrial Affairs

Date of birth: July 16, 1961.

Brendan O'Callaghan joined Sanofi on January 1, 2015. He joined the Executive Committee on October 1, 2021.

Brendan graduated in chemical engineering from the University College of Dublin, where he currently serves as an honorary adjunct Professor of Chemical and Biochemical Engineering.

Brendan joined Sanofi in 2015 and was previously Global Head of Biologics and Industrial Affairs Head of the Specialty Care portfolio. He has played a key role in supporting our transformation to a fully integrated BioPharma company and advancing the digital transformation of our manufacturing network.

Prior to Sanofi, Brendan worked at Schering-Plough before moving to Merck/MSD as Head of Biologics and later Vice President of its Europe, Middle East and Africa Operations.

Brendan O'Callaghan is a citizen of Ireland.

Julie Van Ongevalle

Executive Vice President, Consumer Healthcare

Date of birth: November 22, 1974.

Julie Van Ongevalle joined Sanofi on September 1, 2020.

She graduated from the *Institut Catholique des Hautes Études Commerciales* (Belgium) with a Master of Science in Commercial and Financial Sciences.

With over 20 years of international experience, Julie has a deep knowledge of consumers and digital, as well as a proven track record in brand building, from identifying growth opportunities to building and implementing delivery strategies.

Prior to joining Sanofi, Julie worked at the Estée Lauder Companies, where she held roles of increasing responsibility across the company, starting in 2004. As Global Brand President of the Origins brand from 2016, she led a global organization of 4,000 people, growing the company's market share across geographies. Prior to Origins, she spent eight years in the M.A.C. Cosmetics division, first as General Manager Benelux, then of the EMEA Region and finally North America.

Julie started her career as a marketing manager at GSK Consumer Healthcare and Clinique.

Julie Van Ongevalle is a citizen of Belgium.

Roy Papatheodorou

Executive Vice President, General Counsel & Head of Legal, Ethics & Business Integrity

Date of birth: May 15, 1978.

Roy Papatheodorou joined Sanofi on February 1, 2022.

Priori to joining Sanofi, Roy was General Counsel of Novartis Pharmaceuticals. He has a wealth of experience in leading global and diverse teams, having also headed the Legal Transactions team at Novartis and having previously been the General Counsel of the Actavis Group, one of the largest generics companies at the time.

He started his career at international law firm Linklaters, where he specialized in international M&A, corporate and private equity based in London, with time also spent in Russia and Brazil

Roy Papatheodorou is a citizen of Cyprus and Italy.

John Reed

Executive Vice President, Global Head of Research and Development

Date of birth: October 11, 1958.

John Reed holds a B.A. in chemistry from the University of Virginia, Charlottesville and an M.D. and Ph.D. (Immunology) from the University of Pennsylvania School of Medicine.

He began his academic career as a member of the faculty at the University of Pennsylvania in 1988, following a post-doctoral fellowship in Molecular Biology at the Wistar Institute and a residency in Pathology & Laboratory Medicine at the Hospital of the University of Pennsylvania. John Reed subsequently held faculty appointments at several universities including the University of California, the University of Florida and ETH-Zurich.

In 1992, he joined the Sanford-Burnham Medical Research Institute in La Jolla, California, one of the largest independent non-profit biomedical research institutes in the United States. From 2002 to 2013, he served as CEO of the Institute. During his tenure, John Reed ran a highly productive laboratory that generated more than 900 research publications and over 130 patents, was awarded more than 100 research grants, and trained over 100 post-doctoral fellows. He is a Fellow of the American Association for the Advancement of Science (AAAS) and the recipient of numerous honors and awards for his accomplishments in biomedical research.

John Reed has served on multiple editorial boards of research journals, and was scientific founder or co-founder of four biotechnology companies. He has served on the Board of Directors for five publicly traded biopharmaceutical and biotechnology companies and on the governing boards for various non-profit biomedical research organizations.

From 2013 to 2018, John Reed was Global Head of Roche Pharmaceutical Research & Early Development, based at company headquarters in Basel, Switzerland. He was responsible for research through Phase IIb development for all therapeutic areas, overseeing R&D activities across seven global sites.

He assumed his current position as Executive Vice President, Global Head of Research & Development for Sanofi in July 2018.

John Reed is a citizen of the United States of America.

Arnaud Robert

Executive Vice President, Chief Digital Officer

Date of birth: May 23, 1973.

Arnaud holds an engineering degree from the *École Polytechnique de Montreal*, and a Masters in Engineering and PhD in Computer Science from the Swiss Institute of Technology, Lausanne.

A newcomer to the pharmaceutical sector, Arnaud has led digital transformations across multiple industries and brings solid expertise in e-commerce, customer experience, data and technology; for example, he led the launch of the Apple Watch Nike running app. He previously worked at The Walt Disney Company, Nike, Shaw Communications and most recently as Chief Digital Officer at Viking Cruises.

He was appointed as Chief Digital Officer, leading our digital, data and technology groups, on June 15, 2020.

Arnaud Robert is a citizen of Canada.

Bill Sibold

Executive Vice President, Sanofi Genzyme

Date of birth: October 29, 1966.

Bill Sibold holds an MBA from Harvard Business School and a B.A. in Molecular Biophysics and Biochemistry from the Yale University. He has more than thirty years of experience in the biopharmaceutical industry. Bill Sibold began his career with Eli Lilly and then held a number of leadership positions within Biogen, including driving their US commercial operations in neurology, oncology and rheumatology. He also worked for Biogen in Australia and the Asia-Pacific region, and served as Chief Commercial Officer at Avanir Pharmaceuticals. Bill Sibold joined Sanofi in late 2011 as head of the MS franchise where he oversaw the successful launches of Aubagio® and Lemtrada®. From January 2016 to June 2017 he served as head of Sanofi Genzyme's Global Multiple Sclerosis, Oncology and Immunology organization, where he led preparation for the global launches of dupilumab and sarilumab.

Bill Sibold has headed up Sanofi Genzyme, our specialty care global business unit, since July 1, 2017. He has also served as President for North America since February 2020.

Bill Sibold is a citizen of Canada and of the United States of America.

Thomas Triomphe

Executive Vice President, Head of Sanofi Pasteur

Date of birth: August 6, 1974.

Thomas Triomphe earned his MSc in industrial engineering from École des Ponts ParisTech and the IFP School, and he also holds an MBA from INSEAD.

Thomas joined Sanofi Pasteur in 2004 and has since advanced within the company in several roles of increasing responsibility in sales and marketing at country, regional and global levels. From 2015 to 2018, he was Head of the Asia-Pacific Region, based in Singapore. Before that, he served as Head of Sanofi Pasteur Japan from 2012 to 2015. In 2010, he became Associate Vice President, Head of

the Influenza-Pneumo Franchise after three years as Director for the same franchise, based in the United States. Earlier in his career, Thomas worked in banking and strategic consulting.

Thomas served as Vice President and Head of Franchise & Product Strategy for Sanofi Pasteur from January 2018, in which position he implemented the strategy for our vaccine franchises, in close collaboration with Industrial Affairs and R&D.

He was appointed to his current position on June 15, 2020.

Thomas Triomphe is a citizen of France.

B. Compensation

Compensation and other arrangements for corporate officers

Compensation policy for corporate officers

This section describes the compensation policy for corporate officers of Sanofi, as established pursuant to Article L. 22-10-8 of the French Commercial Code. That policy describes all the components of compensation awarded to corporate officers of Sanofi as consideration for holding office, and explains the process by which it is determined, divided, reviewed and implemented.

Our compensation policy for corporate officers has three distinct elements: (i) the compensation policy for directors; (ii) the compensation policy for the Chairman of the Board; and (iii) the compensation policy for the Chief Executive Officer.

Each of those policies is submitted for approval by our shareholders at the Annual General Meeting, in accordance with Article L. 22-10-8 II of the French Commercial Code. The compensation policy approved in any given year applies to any person holding corporate office in that year. Moreover, when a corporate officer is appointed between two Annual General Meetings, their compensation is defined applying the terms of the compensation policy approved by the most recent Annual General Meeting of shareholders.

Process for determining the compensation policy for corporate officers

The compensation policy for corporate officers is established by the Board of Directors, acting on the recommendation of the Compensation Committee. The Board of Directors applies the AFEP-MEDEF Code when determining the compensation and benefits awarded to our executive and non-executive corporate officers.

All members of the Compensation Committee are independent, and were chosen for their technical competencies and their good understanding of current standards, emerging trends and Sanofi's practices.

To fulfill their remit, the Committee regularly invites the Chief People Officer and the Head of Reward and Performance of the Group to attend their meetings, although the latter absent themselves when the Committee deliberates. Committee members also work with the Chairman and the Secretary to the Board, who have contacts with our principal institutional shareholders ahead of the Annual General Meeting.

In addition, the Chairman of the Committee:

- discusses the financial, accounting and tax impacts of the proposed compensation policy with the Chairman of the Audit Committee;
- plays an active role at meetings of the Appointments, Governance and CSR Committee and the Strategy Committee (to both of which he belongs), thereby gaining assurance that the proposed performance criteria are consistent and appropriate in light of Sanofi's strategic ambitions.

The compensation policy is not subject to annual review, although some arrangements for implementing the policy – such as the performance criteria applicable to the Chief Executive Officer's annual variable compensation, for example – are defined by the Board of Directors on an annual basis.

After consulting the Compensation Committee and as the case may be the other Board Committees, the Board of Directors may, under the second paragraph of item III of Article L. 225-37-2 of the French Commercial Code, temporarily derogate from the approved compensation policy for the Chief Executive Officer in exceptional circumstances and to the extent that the changes are aligned on the corporate interest and necessary to safeguard the continuity or viability of Sanofi. Derogations from the approved policy are possible in respect of the performance conditions applied to the Chief Executive Officer's compensation, and may result in either an increase or a decrease in compensation. The circumstances in which it is possible to apply such a derogation are (i) a change in the structure of the Sanofi group or (ii) major events affecting the markets. Such derogation may only be temporary and must be properly substantiated. Moreover, it will remain subject to approval by the next General Meeting of Sanofi shareholders.

General principles and objectives

Our compensation policy is based on the following general principles:

- the policy must be simple;
- the policy must prioritize long-term performance;
- the level of compensation must be competitive, so that we can attract and retain talent;
- there must be a fair balance between the corporate interest, the challenges of delivering on our strategy, and the expectations of our stakeholders.

The Compensation Committee must ensure that trends in the compensation of corporate officers over the medium term are not uncorrelated with trends in the compensation of all our employees. In terms of annual variable compensation and equity-based compensation, the Compensation Committee aims to achieve convergence between the performance criteria applied to our Senior Leaders and those applied to the Chief Executive Officer.

Our equity-based compensation policy, which aims to align employee and shareholder interests and reinforce loyalty to Sanofi, is a critical tool for our worldwide attractiveness as an employer.

With effect from June 2019, grantees of equity based compensation plans (including our Chief Executive Officer) can only be awarded performance shares. Awarding performance shares reduces the dilutive effect of equity based compensation plans while maintaining the same level of motivation for grantees.

Acting on the recommendation of the Compensation Committee, the Board of Directors determines the performance conditions attached to equity-based compensation for all beneficiaries at Sanofi and its subsidiaries worldwide, thereby furthering the attainment of our objectives. Our equity-based compensation plan rules are made available to our shareholders on the governance page of our website (*www.sanofi.com*) in the same form as that distributed to our employees.

The Board of Directors makes any grant of performance shares contingent on multiple, exacting multi-year performance criteria in order to ensure that our equity-based compensation plans incentivize overall performance. Failure to achieve those criteria over the entire performance measurement period results in a reduction or loss of the initial grant.

In order to align equity-based compensation with our long-term performance, performance is measured over three financial years (the "vesting period"). Awards of performance shares are also contingent on continued employment in the Sanofi group during the vesting period, followed by stringent lock-up obligations in the case of the Chief Executive Officer (see below).

The terms of prior awards cannot be reset subsequently, for instance with less exacting performance conditions.

Compensation policy for directors

Directors hold office for a four-year term, as specified in our Articles of Association.

The maximum annual amount of overall compensation that can be allocated to the directors has been set at €2,000,000 since 2020.

The arrangements for allocating the overall annual amount set by the Annual General Meeting between the directors are determined by the Board of Directors, acting on a recommendation from the Compensation Committee. Directors' compensation comprises (i) an annual fixed amount of €30,000, apportioned on a time basis for directors who assumed or left office during the year, and (ii) a variable amount, allocated by the Board according to actual attendance at Board and Committee meetings. As required by the AFEP-MEDEF Code, directors' compensation is allocated predominantly on a variable basis.

The table below shows how the variable amount payable to directors for attendance at Board and committee meetings is determined; the allocation was last changed in 2020.

	Compensation per meeting			
	Directors resident in France	Directors resident outside France but within Europe	Directors resident outside Europe	Chairman/Chairwoman
Board of Directors	€5,500	€8,250	€11,000	N/A
Audit Committee	€8,250	€8,250	€8,250	€11,000
Compensation Committee	€5,500	€8,250	€11,000	€8,250
Appointments, Governance and CSR Committee	€5,500	€8,250	€8,250	€8,250
Strategy Committee	€5,500	€8,250	€11,000	Determined by reference to place of residence
Scientific Committee	€5,500	€8,250	€11,000	Determined by reference to place of residence

On March 3, 2021, the Board of Directors decided that in light of public health protection measures, the deployment of appropriate technical solutions, and practices adopted by other issuers, directors who take part via videoconference would from 2021 onwards receive compensation equivalent to that paid to a director resident in France attending in person. Committee Chairs continue to receive the usual compensation in respect of the Committee they chair.

In any event, the Board continues to encourage directors to attend Board and Committee meetings in person, subject to strict compliance with public health protection measures.

As an exception, in certain cases two meetings held on the same day give entitlement only to a single payment:

- if on the day of a Shareholders' General Meeting, the Board of Directors meets both before and after the Meeting, only one payment is made for the two Board meetings; and
- if on the same day a director participates in a meeting of the Compensation Committee and a meeting of the Appointments, Governance and CSR Committee, only the higher of the two payments is made to cover both meetings.

The introduction of a separate compensation scale depending on whether or not the director is a European resident is intended to take into account the significantly longer travel time required to attend meetings in person.

Directors do not receive any exceptional compensation or equity-based compensation and have no entitlement to a top-up pension plan.

Neither the Chairman of the Board nor the Chief Executive Officer receives any compensation for serving as a director.

Compensation policy for the Chairman of the Board of Directors

The term of office of the Chairman of the Board is the same as that of the other directors (four years), and the Chairman's term is aligned with his term of office as a director.

The compensation policy for the Chairman of the Board is discussed by the Compensation Committee, which then makes a recommendation to the Board of Directors. The Chairman of the Board is not a member of the Committee, and does not attend meetings where his compensation is discussed.

The compensation of the Chairman of the Board of Directors (where the office of Chairman is separate from that of Chief Executive Officer, as is currently the case) consists solely of fixed compensation and benefits in kind and excludes any variable or exceptional compensation, any awards of stock options or performance shares, and any compensation for serving as a director. The Board meeting of February 22, 2022 set the annual fixed compensation awarded to the Chairman of the Board at €800,000 gross, unchanged from 2021.

Where the office of Chairman is separate from that of Chief Executive Officer, the Chairman of the Board is not entitled to the Sanofi top-up defined-contribution pension plan.

Nor is he entitled to a termination benefit or a non-compete indemnity.

The Chairman of the Board does not receive compensation for chairing Board meetings or meetings of the Appointments, Governance and CSR Committee or the Strategy Committee.

Compensation policy for the Chief Executive Officer

General principles

Our Chief Executive Officer is not appointed for a fixed term of office.

The compensation policy for the Chief Executive Officer is established by the Board of Directors, acting on the recommendation of the Compensation Committee. The compensation structure is not subject to annual review and is applicable for as long as it remains unchanged. The arrangements for implementing the policy may vary from year to year; a table showing the changes made to those arrangements in 2022 and 2021 is provided at the end of the present section.

The compensation of the Chief Executive Officer is determined with reference to compensation awarded to the chief executive officers of the following 12 leading global pharmaceutical companies[(1)]: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd. This panel comprises companies that are comparable to Sanofi, with no limitation as to geographical region given that Sanofi operates in a particularly competitive international environment. The panel was expanded in 2020 so that pharmaceutical companies operating in the biotechnology field are better represented. Consistency with market practice is fundamental in order to attract and retain the talents necessary to our success. In 2021, on the basis of the information published as of the date of this Annual Report on Form 20-F, median fixed compensation of the chief executive officers of the aforementioned twelve leading global pharmaceutical companies was in the region of €1,513,000; the median of the annual variable compensation awarded was in the region of €2,297,000; and the median of the long-term compensation awarded (whether equity-based or in cash) represented around 767% of fixed compensation. Within this peer group, Paul Hudson's overall compensation (fixed, variable and equity-based compensation) lies within the first quartile of the compensation paid by the panel companies. The practices of the main CAC 40 companies are also taken into consideration.[(1)]

In light of Sanofi's performance in the period from 2019 through 2021, during which the "Play to Win" strategy was developed and rolled out, the Board meeting of February 22, 2022 considered it appropriate to review the overall amount of compensation awarded to the Chief Executive Officer relative to that awarded to the Chief Executive Officers of the companies in the above-mentioned panel. In this critical key period for the ongoing execution of the Play to Win strategy, the Board decided to increase the Chief Executive Officer's annual fixed compensation and to determine the amount of his equity-based compensation in respect of 2022 such that his overall compensation would increase, while remaining within the limits set by our compensation policy (see below). The other components of his compensation would remain unchanged, and the total compensation of the Chief Executive Officer after those changes would remain within the first quartile of the compensation paid by the panel of companies.

On taking up office

When the Chief Executive Officer is an outside appointment, the Board of Directors may decide, acting on a recommendation from the Compensation Committee, to compensate the appointee for some or all of the benefits he may have forfeited on leaving his previous employer. In such a case, the terms on which the Chief Executive Officer is hired aim to replicate the diversity of what was forfeited, with a comparable level of risk (variable portion, medium-term equity-based or cash compensation).

During the term of office

Compensation structure

Our policy aims at achieving and maintaining a balance in the compensation structure between fixed compensation, benefits in kind, short-term variable cash compensation, and medium-term variable equity-based compensation.

The compensation policy for the Chief Executive Officer is designed to motivate and reward performance by ensuring that a significant portion of compensation is contingent on the attainment of financial, operational and extra-financial criteria that reflect Sanofi's objectives, and are aligned with the corporate interest and with the creation of shareholder value. Variable cash compensation and equity-based compensation are the two principal levers for action, and are intended to align the interests of the Chief Executive Officer with those of our shareholders and stakeholders.

During the meeting that follows the Board meeting held to close off the financial statements for the previous year, the Compensation Committee examines the levels of attainment of variable compensation for that year. In advance of that meeting, the Chief Executive Officer presents the Committee with a report containing narrative and quantitative information necessary to measure attainment of the objectives. The members of the Compensation Committee then discuss the information provided and report to the Board on those discussions, giving an evaluation of the Chief Executive Officer's performance against each of the criteria (determining the level of attainment for quantitative objectives, and evaluating the level of attainment for qualitative objectives).

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(1) Surveys conducted on the basis of data communicated by Pay Governance and Boracay.

Annual fixed compensation

The annual fixed compensation of the Chief Executive Officer was set at €1,300,000 gross upon his appointment in 2019, and has not changed since then.

The amount of fixed compensation is not subject to annual review. It may however be changed, provided that such changes are not material:

- on the appointment of a new Chief Executive Officer, to reflect the new appointee's competencies and/or then current market practice; and
- in exceptional circumstances, to take account of changes in (i) the role or responsibilities of the Chief Executive Officer, for example in terms of market conditions or the size of the Sanofi group or (ii) the performance level of Sanofi over a given period.

The Board meeting of February 22, 2022 decided to increase the annual fixed compensation of the Chief Executive Officer to €1,400,000 gross with effect from 2022, for reasons explained in the "General principles" section above.

Annual variable compensation

Annual variable compensation is in a range between 0% and 250% of fixed compensation, with a target of 150%. It is subject to a range of varied and exacting performance criteria, both quantitative and qualitative. The criteria are reviewed annually in light of the strategic objectives determined by Sanofi. The Board of Directors sets the criteria for each year at the start of that year on the recommendation of the Compensation Committee. For 2022, the criteria are:

- 50% based on financial indicators published by the Company: sales growth, business net income, free cash flow and business operating income (BOI) margin and growth in new assets, each accounting for 10%. Free cash flow and BOI margin were chosen because they are in line with the Company's strategic roadmap; and
- 50% based on specific individual objectives (1/3 being quantitative objectives), including one linked to corporate social responsibility criteria for Sanofi (partly quantifiable), underlining the Board's commitment to long-term value creation. The individual objectives set for variable remuneration for 2022 are described in "— Compensation and benefits of all kinds awarded to corporate officers in respect of 2022" below.

The percentage of variable compensation linked to the attainment of quantitative criteria may be scaled down regardless of actual performance, in order to give greater weight to the attainment of qualitative criteria. This flexibility can only operate to reduce the amount of variable compensation, and cannot compensate for underperformance on quantitative criteria.

The policy does not allow for the possibility of clawing back any annual variable compensation.

Payment of annual variable compensation in a given year in respect of the previous year is contingent on a favorable shareholder vote at the Annual General Meeting.

Equity-based compensation

The Chief Executive Officer's equity-based compensation, which since June 2019 can only be in the form of performance shares, may not exceed 250% of his target short-term compensation (fixed plus variable).

The Chief Executive Officer's equity-based compensation is contingent upon attainment of exacting performance conditions measured over a three-year-period. Such awards are contingent upon both:

- internal criteria based upon business net income (BNI) and free cash flow (FCF); and
- an external criterion based upon total shareholder return (TSR) relative to a benchmark panel of twelve of the leading global pharmaceutical companies: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.

The valuation of performance shares is calculated at the date of grant, weighted between (i) fair value determined using the Monte Carlo model and (ii) the market price of Sanofi shares at the date of grant, adjusted for dividends expected during the vesting period.

Each award to our Chief Executive Officer takes into account previous awards and his overall compensation. In any event, the maximum number of shares to be delivered may not be more than the number of performance shares initially awarded.

For details of the award to the Chief Executive Officer in respect of 2022, refer to "— Compensation and benefits of all kinds awarded to corporate officers in respect of 2022" below.

Share ownership and lock-up obligation of the Chief Executive Officer

The Chief Executive Officer is bound by the same obligations regarding share ownership specified in our Articles of Association and Board Charter as our other corporate officers.

In addition, until he ceases to hold office the Chief Executive Officer is required to retain a quantity of Sanofi shares equivalent to 50% of any gain (net of taxes and social contributions) arising on the vesting of performance shares, calculated as of the date on which those shares vest. Those shares must be retained in registered form until he ceases to hold office.

In compliance with the AFEP-MEDEF Code and our Board Charter, the Chief Executive Officer must undertake to refrain from entering into speculative or hedging transactions.

Multi-year variable compensation

The Chief Executive Officer does not receive multi-year variable compensation.

Compensation for serving as a director

Executive officers of Sanofi do not receive any compensation for serving as directors. Consequently, the Chief Executive Officer does not receive compensation in his capacity as a director or as a member of the Strategy Committee.

Exceptional compensation

No exceptional compensation can be awarded to the Chief Executive Officer.

On leaving office

The Chief Executive Officer is entitled to a top-up defined-contribution pension plan, a termination benefit, and a non-compete indemnity.

Such arrangements are part of the overall compensation package generally awarded to executive officers; in line with recommendations of the AFEP-MEDEF code, there are very strict rules about how they are implemented. The termination benefit and non-compete indemnity are intended to compensate for the fact that the Chief Executive Officer may be dismissed at any time.

Each of those benefits is taken into account by the Board of Directors when fixing the overall compensation of the Chief Executive Officer.

Pension arrangements

The Chief Executive Officer is entitled to benefits under the top-up defined-contribution pension plan introduced within Sanofi on January 1, 2020. This is a collective plan falling within the scope of Article 82 of the French General Tax Code. It is also offered to members of our Executive Committee and all senior executives whose position is classified within the Sanofi grade scale as “Executive Level 1 or 2”. The Chief Executive Officer's entitlement under this plan may be withdrawn by a decision of the Board of Directors, but not retroactively.

Under the terms of the plan, the Chief Executive Officer receives an annual contribution the amount of which (subject to attainment of a performance condition) may be up to 25% of his reference compensation (annual fixed and variable cash-based compensation only; all other compensation is excluded). The rights accruing under the plan are those that are generated by the capitalization contract taken out with the insurer, and vest even if the Chief Executive Officer does not remain with Sanofi until retirement. The Chief Executive Officer may elect for the rights to be transferable as a survivor's pension.

The performance condition is as follows:

- if the level of attainment for variable compensation is equal to or greater than the target (i.e. 150% of fixed compensation), 100% of the contribution is paid;
- if the level of attainment for variable compensation is less than 100% of fixed compensation, no contribution is paid; and
- between those two limits, the contribution is calculated on a prorata basis.

Because this performance condition is linked to the attainment of the performance criteria for annual variable compensation (which itself is determined with reference to the strategic objectives of Sanofi), it ensures that no pension contributions could be made in the event that the Chief Executive Officer fails to deliver.

The plan is wholly funded by Sanofi, which pays the full amount of the gross contributions. Because it is treated as equivalent to compensation, the contribution is subject to payroll taxes and employer’s social security charges, and to income tax in the hands of the Chief Executive Officer; all of the above are charged on the basis of the bands, rates and other conditions applicable to compensation, paid and declared on his payslips for the contribution period.

Subject to (i) formal confirmation by the Board of Directors that the performance condition for the previous year has been met and (ii) approval of the Chief Executive Officer's compensation package for that year by the Annual General Meeting of our shareholders, the annual gross contribution is paid as follows:

- 50% as a gross insurance premium to the fund manager; and
- 50% to the Chief Executive Officer, to indemnify him for the social security and tax charges for which he will become immediately liable.

In accordance with Article 39.5 bis of the French General Tax Code, deferred compensation as defined in section 4 of Article L. 22-10.9 of the French Commercial Code can be offset against corporate profits as a taxable expense up to a limit set at three times the annual social security ceiling per beneficiary.

The pension entitlement is not cumulative with (i) any termination benefit paid in the event of forced departure or (ii) any non-compete indemnity.

Termination arrangements

The termination benefit only becomes payable if the departure of the Chief Executive Officer is forced, i.e. in the event of removal from office or resignation linked to a change in strategy or control of the Company. Compensation for non-renewal of the term of office is irrelevant in the case of the Chief Executive Officer, because this office is held for an indefinite term.

In addition, no termination benefit is payable and the arrangement is deemed to have been rescinded in the following circumstances:

- removal from office for gross or serious misconduct *(faute grave ou lourde)*;
- if the Chief Executive Officer elects to leave Sanofi to take up another position;
- if the Chief Executive Officer is assigned to another position within Sanofi; or
- if the Chief Executive Officer takes his pension.

Payment of the termination benefit is contingent upon fulfillment of a performance condition, which is deemed to have been met if the attainment rate for the individual variable compensation objectives exceeded 90% of the target; that condition is assessed over the three financial years preceding the Chief Executive Officer leaving office.

The amount of the termination benefit is capped at 24 months of the Chief Executive Officer’s most recent total compensation on the basis of (i) the fixed compensation effective on the date of leaving office and (ii) the last variable compensation received prior to that date subject to fulfilment of the performance condition.

The amount of the termination benefit is reduced by any amount received as consideration for the non-compete undertaking, such that the aggregate amount of those two benefits may never exceed two years of total fixed and variable compensation.

Non-compete undertaking

In the event of his departure from the Company, the Chief Executive Officer undertakes, during the 12-month period following his departure, not to join a competitor of Sanofi as an employee or corporate officer, or to provide services to or cooperate with such a competitor.

In return for this undertaking, he receives an indemnity corresponding to one year's total compensation, based on his fixed compensation effective on the day he leaves office and on the last individual variable compensation he received prior to that date. This indemnity is payable in 12 monthly installments.

However, the Board of Directors reserves the right to release the Chief Executive Officer from that undertaking for some or all of that 12-month period. In such cases, the non-compete indemnity would not be due for the period of time waived by the Company.

Consequences of the Chief Executive Officer's departure for equity-based compensation

If the Chief Executive Officer leaves Sanofi for reasons other than resignation or removal from office for gross or serious misconduct (in which case any award of equity-based compensation is forfeited in full), the overall allocation percentage is prorated to reflect the amount of time the Chief Executive Officer remained with Sanofi during the vesting period.

If at any time prior to the expiration of the vesting period of his performance shares the Chief Executive Officer joins a competitor of Sanofi as an employee or corporate officer, or provides services to or cooperates with such a competitor, he irrevocably loses those performance shares regardless of any full or partial discharge by the Board of Directors of the non-compete undertaking relating to his office as Chief Executive Officer.

Since 2021, if the Chief Executive Officer retires at statutory retirement age prior to the expiration of the vesting period of his performance shares, the overall allocation rate will be apportioned on a prorata basis to reflect the amount of time for which the Chief Executive Officer remained in the employment of Sanofi during the vesting period.

Summary of benefits awarded to the Chief Executive Officer on leaving office

The table below presents a summary of the benefits (as described above) that could be claimed by the Chief Executive Officer on leaving office, depending on the terms of his departure. The information provided in this summary is without prejudice to any decisions that may be made by the Board of Directors.

	Voluntary departure/Removal from office for gross or serious misconduct	Forced departure	Retirement
Termination benefit[(a)]	/	24 months of fixed compensation as of the date of leaving office + 24 months of most recent individual variable compensation received[(d)] – Amounts received as non-compete indemnity	/
Non-compete indemnity[(b)]	12 months of fixed compensation as of the date of leaving office + 12 months of most recent individual variable compensation received prior to leaving office	12 months of fixed compensation as of date of leaving office + 12 months of most recent individual variable compensation received prior to leaving office[(e)]	/
Top-up pension[(c)]	/	/	Annual contribution of up to 25% of reference compensation
Performance share plans not yet vested	Forfeited in full	Rights retained prorata to period of employment within Sanofi[(f)]	Rights retained prorata to period of employment within Sanof[(f)]

(a) The amount of the termination benefit is reduced by any indemnity received as consideration for the non-compete undertaking, such that the aggregate amount of those two benefits may never exceed two years of total fixed and variable compensation.

(b) The Board of Directors may decide to release the Chief Executive Officer from the non-compete undertaking for some or all of the 12-month period. In that case, the non-compete indemnity would not be due, or would be scaled down proportionately.

(c) Defined-contribution pension plan, within the scope of Article 82 of the French General Tax Code. Subject to fulfillment of the performance condition, assessed annually.

(d) Subject to fulfillment of the performance condition assessed over the three financial years preceding departure from office, as described above.

(e) Subject to the Board of Directors enforcing the non-compete undertaking, the amount of the termination benefit is reduced by any indemnity received as consideration for the non-compete undertaking, such that the aggregate amount of those two benefits may never exceed two years of total fixed and variable compensation.

(f) In this case, the Chief Executive Officer remains subject to the terms of the plans, including the performance conditions and the non-compete clause.

The table below summarizes adjustments made to how the compensation policy for the Chief Executive Officer is implemented. They have been thoroughly discussed with our shareholders.

2022	2021
• Annual fixed compensation: – Annual fixed compensation is increased to €1,400,000 gross with effect from 2022. • Annual variable compensation: – Sanofi now publishes the content of the individual CSR performance objective (sub-criteria). • Variable equity-based compensation: – The external criterion based on Total Shareholder Return (TSR) will no longer be measured in absolute value (ranking) but in relative terms (variation from the previous ranking), except that for the Chief Executive Officer any TSR-linked payment will remain contingent on Sanofi achieving a rank greater than or equal to the median of the TSR panel	• Annual variable compensation: – The quantitative component of the objectives (financial and non financial) has been changed from 60% to 67% (minimum). – Sanofi now publishes the level of attainment of non-financial objectives, on an ex post basis. • Equity-based compensation: – If the Chief Executive Officer takes retirement at the statutory retirement age before the end of the vesting period, the overall allocation rate is apportioned on a prorata basis to reflect the amount of time for which he remained in the employment of Sanofi during the vesting period.

Arrangements in favor of executive officers in office as of December 31, 2021 (table No. 11 of the AFEP-MEDEF Code)

Executive officer	Contract of employment	Top-up pension plan	Indemnities or benefits payable or potentially payable on cessation of office	Indemnities payable under non-compete clause
Chairman of the Board	No	No	No	No
Chief Executive Officer	No	Yes	Yes	Yes

Compensation and benefits of all kinds paid during 2021 or awarded in respect of 2021 to corporate officers

The section below constitutes the report on compensation of corporate officers required by Article L. 225-37 of the French Commercial Code. The arrangements described therein will be submitted for approval by our shareholders at the Annual General Meeting called to approve the financial statements for the year ended December 31, 2021 pursuant to Article L. 22-10-34 of the French Commercial Code.

Because the COVID-19 pandemic did not have a major impact on the performance of Sanofi, we did not consider adjusting any elements of the compensation of corporate officers in respect of 2021.

Compensation elements and benefits of all kinds paid during 2021 or awarded in respect of 2021 to directors (table No. 3 of THE AFEP-MEDEF Code)

The compensation policy for directors (as described above in the section entitled "— Compensation policy for directors") defines the fixed amount of compensation, and the principles for allocating the variable portion between directors, up to the limit of the overall amount approved by the Annual General Meeting.

Directors' compensation includes an annual fixed payment, apportioned on a time basis for directors who assumed or left office during the year; and a variable amount, allocated by the Board according to actual attendance at Board and Committee meetings. As required by the AFEP-MEDEF Code, directors' compensation is allocated predominantly on a variable basis.

For 2021, directors' compensation was determined in accordance with the compensation policy for directors as described above in the section entitled "— Compensation policy for directors".

The table below shows amounts paid in respect of 2021 and 2020 to each member of our Board of Directors, including those whose term of office ended during those years.

Directors' compensation for 2020, the amount of which was approved at the Board meeting of March 3, 2021, was partially paid in July 2020, with an additional payment in 2021.

Directors' compensation for 2021, the amount of which was approved at the Board meeting of February 22, 2022, was partially paid in July 2021, with an additional payment in 2022.

(€)	Compensation in respect of 2021			Compensation in respect of 2020		
Name	**Fixed portion**	**Variable portion**	**Total amount (fixed + variable portion)**	**Fixed portion**	**Variable portion**	**Total gross compensation**
Laurent Attal[(a)]	10,000	33,000	43,000	30,000	79,750	109,750
Emmanuel Babeau[(b)]	N/A	N/A	N/A	15,000	42,625	57,625
Christophe Babule	30,000	99,000	129,000	30,000	49,500	79,500
Bernard Charlès[(a)]	10,000	16,500	26,500	30,000	44,000	74,000
Rachel Duan	30,000	88,000	118,000	20,000	24,750	44,750
Claudie Haigneré[(c)]	N/A	N/A	N/A	10,000	27,500	37,500
Lise Kingo	30,000	68,750	98,750	20,000	24,750	44,750
Patrick Kron	30,000	118,250	148,250	30,000	93,500	123,500
Wolfgang Laux[(d)(h)]	20,000	22,000	42,000	N/A	N/A	N/A
Barbara Lavernos[(e)]	20,000	27,500	47,500	N/A	N/A	N/A
Fabienne Lecorvaisier	30,000	115,500	145,500	30,000	110,000	140,000
Melanie Lee[(f)]	30,000	107,250	137,250	30,000	88,000	118,000
Suet-Fern Lee[(c)]	N/A	N/A	N/A	10,000	30,250	40,250
Marion Palme[(a)(f)(h)]	10,000	N/A	10,000	30,000	33,000	63,000
Carole Piwnica	30,000	82,500	115,250	30,000	57,750	87,750
Gilles Schnepp	30,000	121,000	151,000	18,300	27,500	45,800
Christian Senectaire[(a)(h)(i)]	10,000	22,000	32,000	30,000	44,000	74,000
Diane Souza[(g)]	30,000	137,500	167,500	30,000	104,500	134,500
Thomas Südhof[(g)]	30,000	115,500	145,500	30,000	115,500	145,500
Yann Tran (h)(i)(j)	20,000	22,000	42,000	N/A	N/A	N/A
Total	**400,000**	**1,199,000**	**1,599,000**	**423,300**	**996,875**	**1,420,175**
Total			**1,599,000**			**1,420,175**

The amounts reported are gross amounts before taxes.

(a) Director who left office on April 30, 2021.
(b) Director who left office on May 22, 2020.
(c) Director who left office on April 28, 2020.
(d) Director appointed by the European Works Council.
(e) Director appointed by the General Meeting of April 30, 2021.
(f) Director resident outside France but within Europe.
(g) Director resident outside Europe.
(h) Director representing employees.
(i) Compensation due to Christian Senectaire and Yann Tran is paid directly to Fédération Chimie Energie CFDT.
(j) Director appointed by the CFDT, the leading trade union organization with Sanofi in France.

Each of the two directors representing employees has a contract of employment with a Sanofi subsidiary, under which they receive compensation unrelated to their office as director. Consequently, that remuneration is not disclosed.

Variable compensation allocated to directors in respect of 2021 represented 75% of their total compensation.

Compensation and benefits of all kinds paid during 2021 or awarded in respect of 2021 to Serge Weinberg, Chairman of the Board of Directors

Serge Weinberg has held the office of Chairman of the Board of Directors since May 17, 2010. He has never had, and does not currently have, a contract of employment with Sanofi.

The Chairman of the Board is a member of the Appointments, Governance and CSR Committee (which he chaired until December 15, 2021), the Scientific Committee and the Strategy Committee.

The remit of the Chairman of the Board is specified in the Board Charter, which is reproduced in its entirety in Exhibit 1.2. to this Annual Report on Form 20F.

During the course of 2021, the Chairman's activities included:

- chairing all the meetings of the Board of Directors (eight in 2021) and of the Committees of which he is a member (four meetings of the Appointments, Governance and CSR Committee, five meetings of the Strategy Committee and three meetings of the Scientific Committee), and participating in Committee meetings to which he was invited (Audit Committee and Compensation Committee);
- close monitoring of the proper implementation of the decisions taken by the Board;
- meetings with directors, including (i) on the appointment of Barbara Lavernos and the arrival on the Board of two new directors representing employees, to explain to them how the Board operates and answer their questions, (ii) in connection with the evaluation of the Board's operating procedures, and (iii) on matters relating to the projects presented to the Board;

- regular meetings with the members of the Executive Committee;
- meetings with Sanofi employees;
- meetings with biotechs and medtechs;
- organizing two strategy seminars, in March and October 2021;
- representing Sanofi at events or official meetings (in France and abroad) with representatives of the public authorities and other stakeholders, in line with his remit as defined by the Board Charter; and
- participating in the preparation and implementation of Future4Care.

The Chairman also has a role in explaining positions taken by the Board within its sphere of competence, especially in terms of strategy, governance and executive compensation. In furtherance of this role, Serge Weinberg drew on his experience of corporate communication in:

- answering letters from investors and shareholders;
- holding meetings with certain shareholders and proxy advisors; and
- attending a meeting of the Individual Shareholders Committee at Sanofi headquarters in March 2021, discussing what Sanofi had achieved in 2020 and answering questions about the Company's latest news, future prospects and dividend policy.

Those tasks were carried out in coordination with the Chief Executive Officer.

Compensation awarded in respect of the 2021 financial year

On March 3, 2021, acting on a recommendation from the Compensation Committee, the Board of Directors determined the components of Serge Weinberg's compensation for the 2021 financial year, taking into account the nature of his duties and the level of his involvement in the work of the Board and in broader corporate governance matters.

For the 2021 financial year, Serge Weinberg's annual fixed compensation was €800,000, unchanged from 2020.

In line with our compensation policy for the Chairman of the Board, as approved by our shareholders at the Annual General Meeting of April 30, 2021, he did not receive any variable compensation and was not awarded any stock options or performance shares. He received no compensation for serving as a director, and no compensation from any company included in Sanofi's scope of consolidation within the meaning of Article L. 233-16 of the French Commercial Code.

The amount reported for benefits in kind (€7,740 in 2021) relates to a company car with a driver.

Serge Weinberg is not covered by the Sanofi defined-contribution pension plan.

Compensation, options and shares awarded to Serge Weinberg (table No. 1 of the AFEP-MEDEF Code)

(€)	2021	2020
Compensation awarded for the year (details provided in the following table)	807,740	807,715
Valuation of stock options awarded during the year	N/A	N/A
Valuation of performance shares awarded during the year	N/A	N/A
Valuation of other long-term compensation plans	N/A	N/A
Total	**807,740**	**807,715**

Compensation awarded to Serge Weinberg (table No. 2 of the AFEP-MEDEF Code)

	2021		2020	
(€)	Amounts due	Amounts paid	Amounts due	Amounts paid
Fixed compensation[(a)]	800,000	800,000	800,000	800,000
Annual variable compensation	N/A	N/A	N/A	N/A
Exceptional compensation	N/A	N/A	N/A	N/A
Compensation for serving as a director	N/A	N/A	N/A	N/A
Benefits in kind	7,740	7,740	7,715	7,715
Total	**807,740**	**807,740**	**807,715**	**807,715**

The amounts reported are gross amounts before taxes.

(a) Fixed compensation due in respect of a given year is paid during that year.

Compensation and benefits of all kinds paid during 2021 or awarded in respect of 2021 to Paul Hudson, Chief Executive Officer

Paul Hudson has served as Chief Executive Officer of Sanofi since September 1, 2019, and holds office for an indeterminate period.

Paul Hudson does not have a contract of employment with Sanofi, and receives no compensation from any company included in Sanofi's scope of consolidation within the meaning of Article L. 233-16 of the French Commercial Code.

Compensation awarded to Paul Hudson (table No. 1 of the AFEP-MEDEF Code)

(€)	2021	2020
Compensation awarded for the year (details provided in the following table)	5,635,470	5,693,842 [(a)]
Valuation of performance shares awarded during the year[(a)]	5,347,500	5,708,250
Total	**10,982,970** [(b)]	**11,402,092** [(a)]

(a) Weighting between (i) fair value determined using the Monte Carlo model and (ii) market price of Sanofi shares at the date of grant, adjusted for dividends expected during the vesting period

(b) Indicative amount; see footnotes (b) and (c) to the table below.

The parameters used to calculate the valuations are market parameters available in the financial press.

Fixed and variable compensation awarded to Paul Hudson (table No. 2 of the AFEP-MEDEF Code)

	2021		2020	
(€)	Amounts due	Amounts paid	Amounts due	Amounts paid
Fixed compensation [(a)]	1,300,000	1,300,000	1,300,000 [(a)]	1,300,000
Annual variable compensation[(b)]	2,308,800	2,213,250	2,213,250	650,000
Cash bonus (sign-on bonus)[(b)]	2,017,672 [(d)]	2,011,750	2,011,750 [(c)]	N/A
Exceptional compensation	N/A	N/A	N/A	N/A
Compensation for serving as a director	N/A	N/A	N/A	N/A
Benefits in kind	8,998	8,998	168,842	168,842
Total	**5,635,470** [(e)]	**5,533,998**	**5,693,842**	**2,118,842**

The amounts reported are gross amounts before taxes.

(a) Fixed compensation due in respect of a given year is paid during that year.

(b) Variable compensation in respect of a given year is determined at the start of the following year and paid after the Annual General Meeting in that year, subject to shareholder approval.

(c) Cash bonus in respect of the 2020 financial year (First Tranche of the Phantom Stock Units plan), vesting of which is subject to performance conditions (see separate section below). The Board meeting of March 3, 2021 formally noted the attainment level of the performance conditions, and the overall allocation rate. Paul Hudson was awarded 25,000 Phantom Stock Units in respect of 2020. The amount mentioned corresponds to the final valuation of the 25,000 Phantom Stock Units, determined as of March 30, 2021 (the vesting date of the First Tranche).

(d) Cash bonus in respect of the 2021 financial year (Second Tranche of the Phantom Stock Units plan), vesting of which is subject to performance conditions (see separate section below). The Board meeting of February 22, 2022 formally noted the attainment level of the performance conditions, and the overall allocation rate. Paul Hudson was awarded 25,000 Phantom Stock Units in respect of 2021. The amount mentioned in this table is provided by way of indication, and is determined by reference to the average opening price of Sanofi shares on Euronext Paris during the 20 trading days immediately preceding February 22, 2022, the date of the Board meeting that determined the components of the Chief Executive Officer's compensation.The final valuation of the 21,775 Phantom Stock Units will be determined as of March 31, 2022 (the vesting date of the Second Tranche). It will be equal to the total number of Phantom Stock Units multiplied by the value of Sanofi shares (determined by reference to the average opening price of Sanofi shares on Euronext Paris during the 20 trading days immediately preceding the vesting date), and will be communicated on the Sanofi corporate website. Payment of the bonus is contingent on Paul Hudson remaining in post as of March 31, 2022 and is subject to approval by the Annual General Meeting to be held on May 3, 2022.

(e) Indicative amount; see note (d) above.

Fixed and variable compensation

On February 22, 2022, acting on a recommendation from the Compensation Committee, the Board of Directors determined the components of Paul Hudson's compensation for the 2021 financial year.

The Chief Executive Officer's annual compensation for 2021 comprises (i) annual fixed gross compensation of €1,300,000 and, in line with our compensation policy for the Chief Executive Officer as approved by our shareholders at the Annual General Meeting of April 30, 2021 and (ii) annual variable compensation in a range from 0% to 250% of his annual fixed compensation, with a target of 150%, and subject to both quantitative and qualitative criteria.

The objectives applicable to annual variable compensation are 50% based on financial indicators (sales growth, business net income, free cash flow, BOI margin and growth of new assets, each accounting for one-fifth), and 50% based on specific individual objectives. For 2021, the individual objectives set by the Board were:

- business transformation (15%) – *qualitative objective;*
- organization and people (7.5%) – *qualitative objective;*
- development pipeline (12.5%) – *quantitative objective;* and
- CSR (15%) – *quantitative and qualitative objective.*

At the start of 2021, the Board established a precise matrix for determining each individual objective. For confidentiality reasons, neither the level of attainment required (target) for the quantitative criteria nor the details of the qualitative criteria can be disclosed; however, they were pre-determined on a precise basis. In evaluating those criteria, the performance of major global pharmaceutical companies is always taken into account.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of February 22, 2022 reviewed the attainment level of each criterion and sub-criterion. The Board's conclusions are summarized in the table below.

Criterion	Type	Weight	Target/ Maximum (as % of fixed compensation)	Attainment level	Comments	Payout (as % of fixed compensation)
Financial objectives						
Sales growth	Quantitative	10%	15% / 25%	126.0%	Confidential target, Performance above budget	18.91%
Business net income	Quantitative	10%	15% / 25%	126.5%	Confidential target, Performance above budget	18.98%
Free Cash Flow	Quantitative	10%	15% / 25%	117.1%	Confidential target, Performance above budget	17.57%
BOI margin	Quantitative	10%	15% / 25%	102.7%	Confidential target, Performance on budget	15.40%
Growth in new key assets	Quantitative	10%	15% / 25%	97.6%	Dupixent® and China new assets above budget, vaccines below (US flu, China)	14.64%
Individual objectives						
Business Transformation	Quantitative / Qualitative	15%	22.5% / 37.5%	121.0%	Significant progress in the transformation of CHC (digitization, OTC switches, e-commerce, carve in), Industrial Affairs (EUROAPI, digitization, cost of sales), Digital (increase in healthcare professional and patient engagement in General Medicines, governance in place), Vaccines (mRNA center of excellence).	27.23%
Organization and People	Quantitative / Qualitative	7.5%	11.25% / 18.75%	130.0%	Increase in number of women recruited to Grade 5 posts and higher grades. Progress in culture shift, in succession planning of Executive Committee members, and in diversity of succession pipeline.	14.63%
CSR – Reshape of CSR organization and governance	Quantitative / Qualitative	15%	22.5% / 37.5%	115.0%	CSR organization and governance redefined: Head of CSR in place, country network in place, regular reporting to Executive Committee and Board in place	25.88%
CSR – Enhancement of Sanofi's commitments in CSR					• Clear objectives set: 4 pillars / 13 priorities • 58% renewable energy (ahead of target) • Global Health unit officially launched and first core projects ongoing • Definition and launch of the new company ambition, purpose and branding in line with the Play to Win strategy • Reinforced Diversity & Inclusion policy (i.e. 14 weeks of parental leave for all employees)	
CSR – Reinforcement of the monitoring of compliance roadmap / objectives					• Global Compliance Officer, Head of Ethics & Business Integrity hired • Digitization of Ethics & Business Integrity accelerated to strengthen the 360° Integrity and Ethics approach	
Pipeline	Quantitative	12.5%	18.75% / 31.25%	130.0%	Pipeline progression ahead of forecasts: entries into clinical development for 10 First in Class or Best in Class, 8 entries into M2 (Candidate selection), 9 submissions and 10 approvals. Productivity gains ahead of objectives.	24.38%
Total		**100%**	**150% / 250%**	**118.4%**		**177.6%**

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of February 22, 2022, set Paul Hudson's variable compensation for 2021 at €2,308,800, equivalent to 177.6% of his fixed compensation.

Payment of Paul Hudson's variable compensation in respect of the 2021 financial year is contingent on approval of his compensation package by the shareholders in an Ordinary General Meeting, on the terms stipulated in Article L. 22-10-34 II of the French Commercial Code.

Phantom stock units

Having waived all equity-based compensation not yet vested on leaving his previous employer, Paul Hudson was awarded on joining Sanofi a medium-term incentive plan under which he can be paid a cash bonus subject to continuous presence and performance

conditions. Under the terms of the plan, which compensates for around 50% of the incentive plans that Paul Hudson waived, he is awarded phantom stock units, vesting of which is contingent on (i) his continuous presence and (ii) attainment of performance conditions, with the attainment level of those conditions to be determined for half of the award, i.e. 25,000 phantom stock units, as of March 30, 2021 (the "First Tranche") and for the other half of the award, i.e. 25,000 phantom stock units, as of March 31, 2022 (the "Second Tranche").

On expiry of the vesting periods mentioned below, the phantom stock units will vest (subject to fulfilment of the performance conditions), entitling Paul Hudson to a cash bonus equal to the total number of phantom stock units multiplied by the value of Sanofi shares, computed as the average of the opening quoted market prices of Sanofi shares on Euronext Paris for the 20 trading days preceding each vesting date.

The phantom stock units are subject to the following performance conditions:

- attainment level for business net income (BNI), counting towards 50% of the final award;
- attainment level for free cash flow (FCF), counting towards 30% of the final award; and
- a performance criterion based on total shareholder return (TSR) as compared with a panel of our peers over each vesting period, counting towards 20% of the final award. In addition to Sanofi, the panel consists of ten companies: AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Pfizer Inc. and Roche Holding Ltd.

The reference periods for assessing the performance conditions relating to BNI and FCF are:

- January 1, 2020 through December 31, 2020, for the 25,000 phantom stock units with a vesting period ended March 30, 2021 (First Tranche); and
- January 1, 2020 through December 31, 2021, for the 25,000 phantom stock units with a vesting period ending March 31, 2022 (Second Tranche).

The reference periods for assessing the performance conditions relating to TSR are:

- 2020 financial year versus 2019 financial year for the 25,000 phantom stock units with a vesting period ended March 30, 2021 (First Tranche); and
- 2021 financial year versus 2019 financial year for the 25,000 phantom stock units with a vesting period ending March 31, 2022 (Second Tranche).

The global allocation rate is calculated using the rules set forth below:

(i) Attainment level for BNI

This performance criterion corresponds to the average actual-to-budget ratio of BNI attained over the entire vesting period. Budgeted BNI will be different from one financial year to the next, and will be approved by the Board of Directors at the beginning of each financial year.

For each financial year within the vesting period, a percentage will be calculated (at constant exchange rates) representing the ratio of actual BNI to budgeted BNI. That ratio is referred to as the "annual actual-to-budget BNI attainment level".

At the end of the vesting period, the arithmetical average of the annual actual-to-budget BNI attainment levels for each financial year in that period (the actual-to-budget BNI attainment level, or "B") will be calculated, and the Board will determine the BNI allocation rate corresponding to that attainment level as indicated below:

BNI actual-to-budget attainment level ("B")	BNI allocation rate
If B is <95%	0%
If B = 95%	50%
If B is >95% but <98%	(50 + [(B - 95) x 16])%
If B is ≥98% but ≤105%	B%
If B is >105% but <110%	(105 + [(B - 105) x 3])%
If B is ≥110%	120%

(ii) Attainment level for free cash flow (FCF)

This performance criterion corresponds to the average actual-to-budget ratio of FCF attained over the entire vesting period.

Budgeted FCF will be different from one financial year to the next, and will be approved by the Board of Directors at the beginning of each financial year.

For each financial year within the vesting period, a percentage will be calculated (at constant exchange rates) representing the ratio of actual FCF to budgeted FCF. That ratio is referred to as the annual actual-to-budget FCF attainment level. At the end of the vesting period, the arithmetical average of the annual actual-to-budget FCF attainment levels for each financial year in that period (the actual-to-budget FCF attainment level, or "F") will be calculated, and the Board will determine the FCF allocation rate corresponding to that attainment level as indicated below:

FCF actual-to-budget attainment level ("F")	FCF allocation rate
If F is <40%	0%
If F is >40% but <80%	[(F - 40) x 1.625]%
If F = 80%	65%
If F is >80% but <100%	*(65 + [(F - 80) x 1.75])%*
If F = 100%	100%
If F is >100% but <120%	F%
If F is ≥120%	120%

(iii) Attainment level for TSR

For the vesting period, the total shareholder return (TSR) performance condition corresponds to the increase in the quoted market price of Sanofi shares plus dividends per share.

The TSR obtained will be compared with that of each of the companies in the panel of peers listed above, and Sanofi will be ranked against those companies. The TSR allocation rate will be assessed on the basis of Sanofi's ranking within the panel, as described below:

TSR allocation rate calculation:

- if Sanofi's TSR is below M, the TSR allocation rate will be 0% – M being the median (i.e. performance of the company ranked sixth);
- if Sanofi's TSR is M, the TSR allocation rate will be 50%;
- if Sanofi's TSR is equal to the intermediate level, the TSR allocation rate will be 100%; the intermediate level equals M + [(H-M)/2];
- if Sanofi's TSR is ≥ H, the TSR allocation rate will be 150% – H being the highest position, i.e. the arithmetic average of the performance of companies in the panel ranked 1st and 2nd; and
- if Sanofi's TSR is above M but below H, the TSR allocation rate will be calculated using linear interpolation.

The number of phantom stock units actually vesting depends on the overall allocation rate, which for each vesting period is the weighted average of the business net income allocation rate (50%), the FCF allocation rate (30%) and the TSR allocation rate for the vesting period (20%).

The Board Meeting of February 22, 2022 determined the attainment applicable to the Second Tranche of phantom stock units and decided to award 21,775 phantom stock units to Paul Hudson.

The attainment level of the Phantom Stock Units performance conditions for 2021 is as follows:

Performance criterion	Attainment level lower & upper limits	Weight	Attainment level	Allocation rate (weighted)
Business Net Income (BNI)	0% to 120%	50%	102.47%	51.23%
Free Cash Flow (FCF)	0% to 120%	30%	119.57%	35.87%
Total Shareholder Return (TSR)	0% to 150%	20%	0%	0
Overall Allocation Rate				**87.10%**

The amount of the cash bonus payable in this respect will be equal to the total number of Phantom Stock Units multiplied by the value of the Sanofi share with reference to the average opening price of the Sanofi share on Euronext Paris during the 20 trading days immediately preceding March 31, 2022 (vesting date). This amount will be disclosed on the Sanofi website under Investors/Corporate Governance/ Compensation. Payment of that amount is contingent on Paul Hudson remaining in post as of March 31, 2022, and is subject to approval by the Ordinary General Meeting of the Chief Executive Officer's compensation package on the terms stipulated in Article L. 22-10-34 II of the French Commercial Code.

Equity-based compensation

Using the authorizations granted by our shareholders via the 24th resolution at the Annual General Meeting of April 30, 2021, and acting on the recommendations of the Compensation Committee, the Board of Directors meeting of the same day decided to award Paul Hudson 75,000 performance shares. The valuation of that award as of April 30, 2021, determined in accordance with IFRS and incorporating a market-related condition, was €5,347,500, equivalent to 4.11 times his fixed compensation.

The entire amount of the award is contingent upon both internal criteria based upon business net income (BNI) and free cash flow (FCF), and upon an external criterion based on total shareholder return (TSR) relative to a benchmark panel of twelve leading global pharmaceutical companies (plus Sanofi): Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.

To align equity-based compensation on our medium-term performance, a three-year period (2021-2023) is used to measure performance.

The above criteria were selected because they align medium-term equity-based compensation on the strategy adopted by Sanofi.

The arrangements relating to these awards are as follows:

- The performance criterion based on BNI accounts for 50% of the award. That criterion corresponds to the ratio, at constant exchange rates, of actual BNI to budgeted BNI. It represents the average actual-to-budget ratio attained over the entire period. Budgeted BNI is derived from the budget as approved by the Board of Directors at the beginning of each financial year. The BNI objective may not be lower than the bottom end of the full-year guidance range publicly announced by Sanofi at the beginning of each year. If the attainment level is less than 95%, the corresponding performance shares are forfeited.

BNI actual-to-budget attainment level ("B")	BNI allocation rate
If B <95%	0%
If B = 95%	50%
If B is >95% but <98%	(50 + [(B - 95) x 16])%
If B is ≥98% but ≤105%	B%
If B is >105% but <110%	(105 + [(B - 105) x 3])%
If B is ≥110%	120%

- The FCF criterion accounts for 30% of the award. This criterion was selected because it is aligned with Sanofi's current strategic objectives, and is transparent both within and outside the company.

The FCF criterion represents the average actual-to-budget FCF ratio attained over the entire period. The award is based on a target FCF, below which some or all of the performance shares are forfeited.

FCF actual-to-budget attainment level ("F")	FCF allocation rate
If F is ≤70%	0%
If F is >70% but <80%	[(F - 70) x 5]%
If F = 80%	50%
If F is >80% but <100%	(50 + [(F – 80) x 2.5])%
If F = 100%	100%
If F is >100% but <120%	F%
If F is ≥120%	120%

- The TSR criterion accounts for 20% of the award. Total shareholder return (TSR) reflects both the appreciation in the value of our shares (the increase in the share price, comparing the average opening quoted market prices from January 1, 2020 through December 31, 2020 and from January 1, 2023 through December 31, 2023) and the value distributed to our shareholders (dividends), i.e. the two sources of return on investment in Sanofi shares. Our TSR is compared with the benchmark panel of twelve companies listed above. The number of performance shares vesting depends upon our position relative to the TSR for the other companies in the panel. Below 70%, the corresponding performance shares are forfeited:
  - median TSR ("M") is the performance of the company ranked 7th in the panel;
  - the upper bound ("H") is the arithmetical average of the performances of the panel companies ranked 1st, 2nd & 3rd; and
  - the intermediate level is calculated as M + [(H–M)/2].
- The TSR allocation rate will be calculated as follows based on Sanofi's ranking within the panel:
  - if Sanofi's TSR is below M, the TSR allocation rate will be 0%;
  - if Sanofi's TSR is M, the TSR allocation rate will be 50%;
  - if Sanofi's TSR is equal to the intermediate level, the TSR allocation rate will be 100%;
  - if Sanofi's TSR is ≥ H, the TSR allocation rate will be 150%; and
  - if Sanofi's TSR is above M but below H, the TSR allocation rate will be calculated using linear interpolation.

Paul Hudson is under an obligation to retain, until he ceases to hold office, a quantity of Sanofi shares equivalent to 50% of any gain (net of taxes and social contributions) arising on the vesting of his performance shares, calculated as of the date on which those shares vest.

In compliance with the AFEP-MEDEF Code and our Board Charter, Paul Hudson has undertaken to refrain from entering into speculative or hedging transactions, and so far as the Company is aware no hedging instruments have been contracted.

We publish in our Annual Report the level of attainment determined by the Board of Directors for performance conditions applicable to equity-based compensation plans awarded to the Chief Executive Officer. The Board believes that disclosing the attainment level allows our shareholders to better understand the demanding nature of the performance conditions.

In the interests of transparency, we disclose below attainment levels and allocation rates for the most recent performance-linked equity-based compensation plans awarded to our Chief Executive Officer (bearing in mind that these do not apply to Paul Hudson, as they were awarded to his predecessor as Chief Executive Officer):

	Attainment level			Allocation rate
	BNI	**ROA**	**TSR**	
May 10, 2017 plans	2017-2019: 101.3%	2017-2019: 100% above target	2017-2019: 0% (9th of 11)	2017-2019: 80.65% i.e. 177,430 stock options and 40,325 performance shares
May 2, 2018 plans	2018-2020: 100.7%	2018-2020: 87.9%	2018-2020: 0% (8th of 11)	2018-2020: 76.72% i.e. 168,784 stock options and 38,360 performance shares
	BNI	**FCF**	**TSR**	
April 30, 2019 plans	2019-2021: 101.99%	2019-2021: 127.67% - capped at 100%	2018-2020: 50% (6th of 11)	2019-2021: 97.00% i.e. 213,400 stock options and 48,500 performance shares

Performance shares awarded to Paul Hudson in 2021 (table No. 6 of the AFEP-MEDEF Code)

Source	Plan date	Valuation of performance shares (€)	Number of performance shares awarded during the period	Vesting date	Availability date[(a)]	Performance conditions
Sanofi	04/30/2021	5,347,500	75,000	04/30/2024	04/30/2024	Yes

(a) Under the terms of our Board Charter, Paul Hudson is required to retain a quantity of shares corresponding to 50% of the capital gain arising on the vesting of the shares, net of the associated taxes and social contributions.

Each performance share awarded on April 30, 2021, was valued at €71.30, valuing the total benefit at €5,347,500.

The General Meeting of April 30, 2021 decided to restrict the number of performance shares that can be awarded to executive officers to 5% of the overall limit (1.5% of the share capital). The number of shares awarded to Paul Hudson in 2021 represents 0.39% of the total limit approved by that Meeting and 0.005% of our share capital at the date of grant.

Performance shares awarded to Paul Hudson which became available in 2021 (table No. 7 of the AFEP-MEDEF Code)

Because Paul Hudson took office on September 1, 2019, he was not awarded any performance shares prior to the 2020 financial year. Consequently, no performance shares became available to him in 2021.

Source	Plan date	Valuation of performance shares (€)	Number of performance shares awarded during the period	Vesting date	Availability date	Performance conditions
Sanofi	—	—	None	—	—	–

Pension rights

Paul Hudson is entitled to benefits under the top-up defined-contribution pension plan introduced within Sanofi on January 1, 2020. Under the terms of the plan, the Chief Executive Officer receives (subject to attainment of a performance condition) an annual contribution of up to 25% of his reference compensation (annual fixed and variable compensation).

The performance condition for the vesting of pension rights is linked to the attainment of the performance criteria for 2021 variable compensation. The Board of Directors, at its meeting of February 22, 2022, ascertained whether that performance condition had been met, noting that the attainment level for the variable portion of Paul Hudson's compensation for the 2021 financial year was 118.40%, i.e. 177.6% of his fixed compensation.

The annual gross contribution is paid as follows:

- 50% as a gross insurance premium to the fund manager – the amount due to the fund manager with respect to 2021 is €451,000; and
- 50% to Paul Hudson, to indemnify him for the social security and tax charges for which he will become immediately liable. The amount due to Paul Hudson with respect to 2021 was set by the Board of Directors at is meeting of February 22, 2022 at €451,000.

Payment of those amounts is contingent on approval of the Chief Executive Officer's compensation package by the shareholders in an Ordinary General Meeting, on the terms stipulated in Article L. 22-10-34 II of the French Commercial Code.

Social welfare and health insurance

Paul Hudson is subject to, benefits from and contributes to the same health cover, and death and disability plans as are applicable to other employees of Sanofi based in France. He also benefits from an unemployment insurance scheme.

Benefits in kind

The benefits in kind received by Paul Hudson in 2021 were valued at €8,998, and correspond to a company car with a driver.

Pay ratio between compensation of executive officers and average/median compensation of Sanofi employees – changes in compensation of executive officers and employees relative to the performance of Sanofi

This information is disclosed in accordance with Article L. 22-10-9 6° of the French Commercial Code, further to the enactment of the "Pacte" law.

Explanations of calculation methods and of year-on-year changes in the executive pay ratio:

- The scope includes Sanofi SA (the parent company) and all of its direct and indirect subsidiaries located in France, and hence covers more than 80% of total payroll of permanent employees in France. No separate ratios are published for Sanofi SA (the parent company), as the low headcount at Sanofi SA means that such ratios would not be representative of our total headcount in France.
- The employee compensation used in the calculation is the full time equivalent (FTE) compensation of permanent employees with at least two financial years of uninterrupted employment.
- Compensation includes fixed compensation awarded during the reference year, and variable compensation related to the previous year and paid during the reference year. All compensation amounts are gross amounts.
- In order to maintain consistency, we have excluded from the numerator (i) compensation items not included in the denominator and (ii) non-recurring compensation items. This applies in particular to accommodation expenses related to the relocation to France of the Chief Executive Officer (Paul Hudson) in 2020, and to expenses related to unemployment insurance.
- Long term variable compensation: performance shares and stock options awarded during each reference year are valued at the date of grant in accordance with international financial reporting standards. The valuation of the performance shares awarded in 2020 that include the Total Shareholder Return (TSR) performance condition incorporates market conditions. Awards are subject to a continuing employment condition (three years minimum) and to performance conditions. Consequently, the valuation at the date of grant is not necessarily indicative of the value of stock options and performance shares at the end of the vesting period, especially if the performance conditions are not met.
- For plans that have expired since 2017, attainment levels were in the region of 81% for the Chief Executive Officer and 100% for the employee plans. For more information about attainment levels and allocation rates for our stock option plans and performance share plans, see "— Item 6.E. — Share Ownership" below.
- Since Olivier Brandicourt (our previous Chief Executive Officer) received the same number of stock options and performance shares each year from 2016 to 2019, fluctuations in the Sanofi share price had a significant impact on the pay ratio during this period.
- Business net income is a non-GAAP financial measure used by Sanofi and consolidated on a worldwide basis. The 2016 and 2017 business net income figures include the impacts of the first-time application of IFRS 15 on revenue recognition (see Note A.2.1.1. to our consolidated financial statements for the year ended December 31, 2018).
- 2018 and 2019 figures have been restated for comparative purposes, to (i) exclude Sanofi's equity-accounted share of Regeneron's net profits (see note D.2. to our consolidated financial statements, included at Item 18 of this Annual Report on Form 20-F) and (ii) include the effects of IFRS 16.
- Regular benchmarking reviews are conducted to ensure that the level of compensation awarded to our employees and CEO is competitive and consistent with pharmaceutical industry levels.

Comparison of compensation of Sanofi executive officers with employee compensation (parent company and all direct and indirect subsidiaries located in France)

Chief Executive Officer[(a)]	2017	2018	2019	2020	2021
Ratio versus average compensation	128.1	93.8	106.6	110.6	111.4
Change in %		-26.8%	13.6%	3.8%	0.7%
Ratio versus median compensation	165.0	120.3	135.4	142.8	142.1
Change in %		-27.1%	12.5%	5.5%	-0.5%

Chairman of the Board (Serge Weinberg)	2017	2018	2019	2020	2021
Ratio versus average compensation	9.2	9.2	9.2	10.0	10.1
Change in %		0.7%	-0.1%	8.4%	1.7%
Ratio versus median compensation	11.8	11.8	11.7	12.9	12.9
Change in %		0.3%	-1.1%	10.1%	0.5%

(a) 2019: Olivier Brandicourt left office on August 31. Paul Hudson was appointed as CEO on September 1, 2019.
2020: The 2020 CEO compensation includes Paul Hudson's 2020 fixed compensation (€1.3 million), his 2019 variable compensation as paid in 2020 and annualized (€1.95 million), and 75,000 performance shares awarded in 2020.

Based on full-time equivalent permanent employees of all Sanofi legal entities worldwide with at least two years of uninterrupted employment, the ratios for 2021 were as follows:

- CEO:
  - ratio versus average compensation: 130; and
  - ratio versus median compensation: 190.5.

- Chairman of the Board of Directors:
  - ratio versus average compensation: 11.8; and
  - ratio versus median compensation: 17.3.

These ratios were calculated on the basis of annualized basic compensation, variable compensation in respect of the previous year, and performance shares awarded during 2021, applying 2021 average exchange rates.

Annual change in compensation, company performance and average employee compensation (parent company and all direct and indirect subsidiaries located in France)

	FY 2016[a]	FY 2017 vs FY 2016	FY 2018 vs FY 2017	FY 2019 vs FY 2018	FY 2020 vs FY 2019[a]	FY 2021 vs 2020[b]
Chief Executive Officer (in € thousand)						
Compensation	7,693	9,916	7,213	8,200	8,958	8,870
Change in € thousand		2,223	(2,703)	987	758	(89)
Change in %		28.89%	-27.26%	13.69%	9.25%	-0.99 %
Chairman of the Board (in € thousand)						
Compensation	708.35	708.35	708.36	708.19	807.72	807.74
Change in € thousand		—	0.01	(0.17)	99.52	0.02
Change in %		—%	—%	-0.02%	14.05%	— %
Average employee compensation on FTE basis (in € thousand)						
Compensation	75.42	77.40	76.87	76.93	80.97	79.59
Change in € thousand		1.98	(0.53)	0.06	4.03	(1.37)
Change in %		2.62%	-0.69%	0.08%	5.24%	-1.69 (c)
Business net income (in € million)						
Business net income	7,308	6,943	6,411	7,050	7,346	8,213
Change in € thousand		(365)	(532)	639	296	867
Change in %		-4.99%	-7.66%	9.97%	4.20%	11.80%

(a) 2015 and 2016: Olivier Brandicourt was appointed as CEO on April 2, 2015. Christopher Viehbacher, his predecessor as CEO, left office on October 29, 2014. The Chairman of the Board, Serge Weinberg, served as interim CEO until the appointment of Olivier Brandicourt, but received no specific compensation for holding that office. Christopher Viehbacher's 2014 compensation and Olivier Brandicourt's 2015 compensation have been annualized for the purpose of calculating the ratios.
2019: Olivier Brandicourt left office on August 31. Paul Hudson was appointed as CEO on September 1, 2019. His 2019 variable compensation, paid in 2020, has been annualized for the purpose of calculating the ratios.

(b) 2020: Paul Hudson took office on September 1, 2019. The 2020 CEO compensation includes Paul Hudson's 2020 fixed compensation (€1.3 million), his 2019 variable compensation paid in 2020 and annualized (€1,950 million), and 75,000 performance shares awarded in 2020.

(c) The change in average employee compensation in France between 2020 and 2021 was driven primarily by differences in the average compensation levels of employees who left the company versus those who joined.

Compensation and benefits of all kinds awarded to corporate officers in respect of 2022

Compensation and benefits of all kinds awarded to directors in respect of 2022

The amounts awarded to directors in respect of 2022 will be determined in accordance with the principles described above in “Compensation policy for directors”, within the section entitled “Compensation policy for corporate officers”.

Compensation and benefits of all kinds awarded in respect of 2022 to Serge Weinberg, Chairman of the Board of Directors

The components of the compensation awarded to the Chairman of the Board of Directors are described above in “Compensation policy for the Chairman of the Board of Directors”, within the section entitled “Compensation policy for corporate officers”.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of February 22, 2022 determined the components of Serge Weinberg’s compensation. Serge Weinberg will receive annual fixed compensation of €800,000 for holding office as Chairman (the same as for the 2021 financial year; see explanations provided in the section entitled “Compensation policy for corporate officers” above).

Serge Weinberg does not receive any variable compensation, stock options or performance shares. In accordance with AMF recommendations, he does not receive any compensation (i) for serving as a director or (ii) from any company included in Sanofi’s scope of consolidation within the meaning of Article L. 233-16 of the French Commercial Code.

His benefits in kind for 2022 comprise a company car with a driver.

Compensation and benefits of all kinds awarded in respect of 2022 to Paul Hudson, Chief Executive Officer

Fixed and variable compensation

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of February 22, 2022 determined the components of Paul Hudson's compensation for the 2022 financial year.

Paul Hudson's annual compensation comprises (i) annual fixed gross compensation of €1,400,000 (see the explanations provided under "Compensation policy for the Chief Executive Officer" in the section entitled "Compensation policy for corporate officers" above) and (ii) annual variable compensation in a range from 0% to 250% of his annual fixed compensation, with a target of 150%, and subject to both quantitative and qualitative criteria.

Those objectives are 50% based on financial indicators (sales growth, business net income, free cash flow, BOI margin, and growth of new assets, each accounting for 10%), and 50% based on specific individual objectives. Those individual objectives, unchanged for 2022, are shown below:

2022 individual objectives		2021 individual objectives	
Business transformation *(CHC, Vaccines, General Medicines, Industrial Affairs, Digital, Specialty Care)*	15%	Business transformation	15%
Organization and people *(Diversity, Culture, Product Portfolio, Succession Pipeline, Evolutive Vaccines Facility, Simplification)*	7.5%	Organization and people	7.5%
Development pipeline *(Preclinical: M1 (Lead selection), M2 (Candidate selection), First in Human, Pivotal Studies, Submissions)*	12.5%	Development Pipeline	12.5%
CSR *(CO2 emissions, Global access plan, Leaders to citizen initiative, launch of the Sanofi Global Health unit, Modernization of Compliance, new ambition Employee Value Proposition, and rollout of new Corporate branding)*	15%	CSR	15%

Equity-based compensation

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of February 22, 2022 proposes awarding 82,500 performance shares to Paul Hudson in respect of 2022. In accordance with the AFEP-MEDEF Code, the entire award will be subject to criteria that are both internal (based on our business net income and free cash flow) and external (based on total shareholder return as compared with 12 leading global pharmaceutical companies: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.).

With effect from the 2022 awards, for Senior Executives (see section 5.E "Share ownership") and the Chief Executive Officer, the TSR criterion will no longer be measured in absolute value (ranking) but in relative terms (variation from the previous ranking). That variation (the "Sanofi TSR Rank Improvement") will be determined by comparing the Endpoint Sanofi TSR Rank (established over a 3-year measurement period) to the Baseline Sanofi TSR Rank (established over a 1-year measurement period). TSR-linked awards would be 50% if the ranking improved by 1, 100% if it improved by 2, and 150% if it improved by 3. For the Chief Executive Officer, any TSR-linked payment will remain contingent on Sanofi achieving an Endpoint Rank greater than or equal to the median of the TSR panel. We will make details of the terms of the plan available to shareholders on the governance page of our corporate website (www.sanofi.com) in advance of the Annual General Meeting of May 3, 2022.

In accordance with the AFEP-MEDEF Code, Paul Hudson is bound by rules on insider trading that impose blackout periods, as contained in our Board Charter.

In accordance with the AFEP-MEDEF Code and with our Board Charter, Paul Hudson has undertaken not to engage in speculative or hedging transactions, and as far as the company as aware no hedging instruments have been contracted.

Transactions in shares by members of the Board of Directors and equivalent persons

As far as Sanofi is aware, transactions in our securities carried out during 2021 by (i) Board members, (ii) executives with the power to make management decisions affecting our future development and corporate strategy and (iii) persons with close personal ties to such individuals (as per Article L. 621-18-2 of the French Monetary and Financial Code), were as follows:

- on December 22, 2021 Barbara Lavernos (director) purchased 500 shares at a price of €87.70 per share.

Service contracts

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors or executive officers providing for any benefits.

Compensation and arrangements for other Executive Committee members

Compensation

The compensation of Executive Committee members other than the Chief Executive Officer is reviewed by the Compensation Committee, taking into consideration the practices of leading global pharmaceutical companies.

In addition to fixed compensation, they receive variable compensation. Their target variable compensation depends on their position, and can represent up to 100% of their fixed compensation. The target amount of individual variable compensation is determined in line with market practice. It rewards the joint contribution of all Executive Committee members to Sanofi's performance.

For 2021, the variable component consisted of two elements:

- attainment of quantitative objectives (accounting for 50%) which are measured at consolidated level: sales growth 30%, ratio of business operating income to net sales ("BOI margin") 35%, research and development outcomes 20%, and free cash flow 15%; and
- attainment of quantitative and qualitative objectives both individually (30%) and collectively (20%) within the Executive Committee (together accounting for 50%).

The indicators used are intended to measure Sanofi's annual performance objectives; individual objectives; and the attainment of people objectives like gender parity in senior executive roles, individual career development plans, and transformation of the corporate culture to align with the "Play to Win" strategy.

In addition, Executive Committee members may be awarded performance shares.

For 2021, the total gross compensation paid and accrued in respect of members of the Executive Committee (excluding the Chief Executive Officer) was €19 million, including €7 million in fixed compensation.

On April 30, 2021 and October 27, 2021, a total of 217,153 performance shares were awarded to members of the Executive Committee (excluding the award to the Chief Executive Officer). No stock options were awarded in 2021 to members of the Executive Committee or the Chief Executive Officer.

In compliance with the AFEP-MEDEF Code, these entire awards are contingent upon two internal criteria, based on business net income (BNI)[(1)], free cash flow (FCF); and on an external criterion, based on total shareholder return (TSR). Those criteria were selected because they align medium-term equity-based compensation with the strategy adopted by Sanofi. The Board believes that the performance conditions applied are good indicators of shareholder value creation in terms of the quality of investment decision and the commitment to deliver exacting financial results in a difficult economic environment.

The arrangements relating to these awards are as follows:

- The BNI performance criterion accounts for 50% of the award. This criterion corresponds to the ratio, at constant exchange rates, of actual BNI to budgeted BNI. It represents the average actual-to-budget ratio attained over the entire period. Budgeted BNI is derived from the budget as approved by the Board of Directors at the beginning of each financial year. The BNI objective may not be lower than the bottom end of the full-year guidance range publicly announced by Sanofi at the beginning of each year. If the ratio is less than 95%, the corresponding performance shares are forfeited.

BNI actual-to-budget attainment level ("B")	BNI allocation rate
If B is <95%	0%
If B = 95%	50%
If B is >95% but <98%	(50 + [(B –95) x 16])%
If B is ≥98% but ≤105%	B%
If B is >105% but <110%	(105 + [(B –105) x 3])%
If B is ≥110%	120%

- The FCF criterion accounts for 30% of the award. It represents the average actual-to-budget ratio of free cash flow attained over the entire period. The award is based on a target FCF, below which some or all of or performance shares are forfeited.

FCF actual-to-budget attainment level ("F")	FCF allocation rate
If F is ≤70%	0%
If F is >70% but <80%	[(F – 70) x 5]%
If F = 80%	50%
If F is >80% but <100%	(50 + [(F – 80) x 2.5])%
If F = 100%	100%
If F is >100% but <120%	F%
If F is >120%	120%

- The TSR criterion accounts for 20% of the award.

For the vesting period, the TSR criterion corresponds to the increase in the quoted market price of Sanofi shares, determined by comparing the average of the opening quoted market prices from January 1, 2020 through December 31, 2020 and the average of the opening quoted market prices from January 1, 2023 to December 31, 2023, plus dividends per share.

(1) Non-GAAP financial measure. For a definition, see "Item 5. – Operating and Financial Review and Prospects – Business Net Income".

The TSR obtained will be compared with that of each of the companies in a panel of peers to generate a ranking that includes Sanofi and the 12 companies in the panel: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.

- Definitions:
  - median TSR (“M”) is the performance of the company ranked seventh in the panel;
  - the upper bound (“H”) is the arithmetical average of the performances of the panel companies ranked first, second and third; and
  - the intermediate level is calculated as M + [(H–M)/2].
- The TSR allocation rate will be calculated as follows based on Sanofi’s ranking within the panel:
  - if Sanofi’s TSR is below M, the TSR allocation rate will be 0%;
  - if Sanofi’s TSR is M, the TSR allocation rate will be 50%;
  - if Sanofi’s TSR is equal to the intermediate level, the TSR allocation rate will be 100%;
  - if Sanofi’s TSR is ≥ H, the TSR allocation rate will be 150%; and
  - if Sanofi’s TSR is above M but below H, the TSR allocation rate will be calculated using linear interpolation.
- With effect from the 2022 awards, for the plan applicable to members of the Executive Committee, the mechanism of the TSR criterion will be modified as follows:
  - the TSR criterion will no longer be measured in absolute value (ranking) but in relative terms (variation from the previous ranking). That variation (the "Sanofi TSR Rank Improvement") will be determined by comparing the Endpoint Sanofi TSR Rank (established over a 3-year measurement period) to the Baseline Sanofi TSR Rank (established over a 1-year measurement period). TSR-linked awards would be 50% if the ranking improved by 1, 100% if it improved by 2, and 150% if it improved by 3; and
  - a multiplier will be applied and will uplift the number of performance shares vesting by 10% if (i) the maximum TSR allocation rate is attained and (ii) Sanofi ranks greater than or equal to the median for the TSR benchmark panel.
- The number of performance shares actually vesting depends on the overall allocation rate, which for the vesting period is the weighted average of the BNI allocation rate (50%), the FCF allocation rate (30%) and the TSR allocation rate for the vesting period (20%).
- In order to align equity-based compensation with medium-term performance, performance is measured over three financial years.
- Vesting is subject to a non-compete clause.
- The entire award is forfeited in the event of resignation, or dismissal for gross or serious misconduct.
- In the event of individual dismissal other than for gross or serious misconduct or retirement before the age of 60, or if the beneficiary’s employer ceases to be part of the Sanofi group, the overall allocation percentage is prorated to reflect the amount of time the person remained with the Sanofi group during the vesting period.
- If any of the following events occur, full rights to the award are retained: (i) dismissal as part of a collective redundancy plan or of an equivalent collective plan negotiated and approved by the Chief Executive Officer of Sanofi; (ii) retirement on or after reaching the statutory retirement age, or early retirement under a statutory or contractual early retirement plan implemented by the relevant Sanofi entity and duly approved by the Chief Executive Officer of Sanofi; (iii) disability classified in the second or third categories stipulated in Article L. 314-4 of the French Social Security Code; or (iv) death of the beneficiary.

Pension arrangements

The total amount accrued as of December 31, 2021 in respect of corporate pension plans for persons who have held an executive position during the year 2021 was €28 million. That amount includes an expense of €1 million recognized in profit or loss during 2021.

For 2021, the total amount of gross compensation paid and accrued to members of the Executive Committee (excluding the Chief Executive Officer) was €19 million, of which €7 million was fixed compensation.

C. Board Practices

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors or corporate officers providing for benefits upon termination of employment. With respect to the Chief Executive Officer, see also "— B. Compensation — Compensation and arrangements for corporate officers" above.

Application of the AFEP-MEDEF Code

The AFEP-MEDEF Code requires us to report specifically on the application of its recommendations and if any of them have not been applied, explain why. Currently our departures from this Code are as follows:

Paragraph of the AFEP-MEDEF Code	Recommendation of the AFEP-MEDEF Code	Application by Sanofi
10.2 Evaluation of the Board of Directors	The evaluation has three objectives: • […]; • measure the actual contribution of each director to the Board's work.	Actual individual contributions are assessed during formal evaluations conducted every three years with the help of a specialist consulting firm, the most recent of which took place at the end of 2021. More generally, the issue of competence and individual contribution to the work of the Board and its Committees is addressed on a continuous basis, with a specific review when a director is up for reappointment as a Board or Committee member. Annual evaluations are conducted using a detailed questionnaire. The questionnaire deals specifically with the operating procedures of the Board and gives directors an opportunity to express freely their assessment of the individual contributions of other directors. These evaluations may be followed by individual meetings with the Secretary to the Board, at which the responses to the questionnaire are analyzed and discussed.
18.1 Membership of the Compensation Committee	It is recommended that one of its members be an employee director.	The Board intends to appoint a director representing employees to the Compensation Committee after an induction period that will give that director time to adapt to how the Company operates, understand its specific characteristics, familiarize himself or herself with the challenges and broad outlines of the Board's remit, and undertake any necessary training.
24.4 Non-competition agreement	In any event, no benefit can be paid over the age of 65.	Under the compensation policy for our Chief Executive Officer, he undertakes in the event he leaves the Company not to join a competitor of the Company as an employee or corporate officer, or to provide services to or cooperate with such a competitor. In return for this undertaking, he receives an indemnity corresponding to one year's total compensation based on his fixed compensation effective on the day he ceases to hold office and the last individual variable compensation received prior to that date. The indemnity is payable in 12 monthly installments. However, the Board of Directors may decide at the time the Chief Executive Officer leaves office (regardless of his age) to release him from the non-compete undertaking for some or all of the 12-month period. In such a case, the non-compete indemnity would not be due for the period of time waived by the Company. The Board of Directors, acting on a recommendation of the Compensation Committee, decided not to alter the compensation policy and non-compete undertaking of the Chief Executive Officer such that his indemnity would not be payable after he reaches the age of 65, on the basis that this is out of line with the actual situation. In practice, many executive officers continue to work after they leave office, often in a consultancy role. Consequently, enforcing such a rule could deprive Sanofi of legal protection in the event that the Chief Executive Officer were to engage in a competing activity immediately after leaving the Company.

Activities of the Board of Directors in 2021

During 2021, the Board of Directors met ten times (including strategy seminars), with an overall attendance rate among Board members of 98%. This attendance rate includes participation by videoconference, which was the preferred method of participating in meetings during 2021 due to the COVID-19 crisis. Individual attendance rates varied between 75% and 100%.

The following persons attended meetings of the Board of Directors:

- the directors;
- the Secretary to the Board;
- frequently: members of the Executive Committee; and
- occasionally: the statutory auditors, managers of our global support functions, and other company employees.

The agenda for each meeting of the Board is prepared by the Secretary after consultation with the Chairman, taking account of the agendas for the meetings of the specialist Committees and the suggestions of the directors.

Approximately one week prior to each meeting of the Board of Directors, the directors each receive a file containing the agenda, the minutes of the previous meeting, and documentation relating to the agenda.

The minutes of each meeting are expressly approved at the next meeting of the Board of Directors.

In compliance with our Board Charter, certain issues are examined in advance by the various Committees according to their areas of competence to enable them to make a recommendation; those issues are then submitted for a decision by the Board of Directors.

Since 2016, acting on a recommendation from the Appointments, Governance and CSR Committee, the Board has held at least two executive sessions (i.e. meetings held without the Chief Executive Officer present) per year. If the Chairman of the Board so decides, such sessions may also be held without the directors representing employees (or any other Sanofi employee) being present. The primary purpose of such sessions is to evaluate the way the Board and its Committees operate, to discuss the performance of the Chief Executive Officer, and to debate succession planning. After a transitional phase in 2020 due to the global COVID-19 pandemic and the arrival of Paul Hudson as CEO, two executive sessions were held in 2021, in March and December.

In 2021, the main activities of the Board of Directors related to the following issues:

Financial statements and financial management	• Review of the individual company and consolidated financial statements for the 2020 financial year and for the first half of 2021, review of the consolidated financial statements for the first three quarters of 2021, and review of draft press releases and presentations to analysts relating to the publication of those financial statements. • Review of forward-looking management documents. • Preparation of the Capital Markets Day presentation. • Presentation of the 2022 budget, and 2022-2024 financial forecasts. • Renewal of the bond issuance program in the United States. • Delegation of authority to the Chief Executive Officer to issue bonds and guarantees. • Renewal of the share repurchase program. • Recording the amount of share capital, reducing the share capital through cancellation of treasury shares, and amending the Articles of Association accordingly.
Operations, strategy and risk management	• Follow-up on implementation of the Play to Win strategy. • Several updates on the situation related to the global COVID-19 pandemic. • An update on progress in vaccine research, including an update on the COVID-19 recombinant vaccine. • Monitoring of the strategy in China. • Review and follow-up of acquisition projects: Kymab,Translate Bio, Kadmon, Tidal Therapeutics, Owkin and Origimm. • Receive an update on the EUROAPI project. • Receive an update on Industrial Affairs. • Receive an update on digital. • Review of the minutes of the Strategy Committee and the Scientific Committee. • Review of Sanofi's 2021 risk management activity report and risk profile analysis. • Review of the new brand policy.

Appointments and governance	• Composition of the Board and its Committees: – proposal to renew the terms of office of Fabienne Lecorvaisier and Melanie Lee as independent directors, and to appoint Barbara Lavernos as director, at the 2021 Annual General Meeting; – appointment of Gilles Schnepp to the Strategy Committee and as Chairman of the Appointments, Governance and CSR Committee, Rachel Duan to the Compensation Committee and Lise Kingo to the Appointments, Governance and CSR Committee. • Review of succession planning for the Chairman and the Chief Executive Officer. • Review of director independence. • Reviews of the Board of Directors' Management Report, the report on corporate governance, and the reports of the statutory auditors. • Arrangements for holding the Annual General Meeting of Shareholders and of Holders of Participating Shares (Series issued in 1983) in light of the COVID-19 crisis; adoption of (i) the draft resolutions, (ii) the report of the Board of Directors on the resolutions, and (iii) the special reports on the awards of stock options and performance shares; and examination of questions submitted by shareholders in writing. • Annual evaluation of the work of the Board and its Committees. • Presentation of a detailed report on the governance roadshows arranged for the main investors in Sanofi. • Proposal to amend the Articles of Association and revisions to the Board Charter. • Review of previously-approved related party agreements. • Update on the Action 2021 employee share ownership plan.
Compensation	• Determination of the compensation of corporate officers (note that the Board deliberates in executive session without the corporate officers present: the situation of the Chairman of the Board of Directors is dealt with first in his absence, and then the Chief Executive Officer's compensation is dealt with in the presence of the Chairman but with the Chief Executive Officer absent): – determination of Paul Hudson's fixed compensation and the objectives of his variable compensation for 2021; and – determination of the 2021 compensation of the Chairman of the Board of Directors. • Directors' compensation: allocation of the amount of directors' compensation for 2020, and changes to the allocation methods for 2021 due to the holding of Board meetings by videoconference. • Review of the fixed and variable compensation of the Executive Committee in 2020 and 2021. • Adoption of the performance share plans for 2021, and determination of the fulfilment of performance conditions of previous equity-based compensation plans.
Corporate Social Responsibility (CSR)	• Monitoring of progress on Sanofi's CSR strategy. • Consideration of CSR criteria applicable to Paul Hudson's annual variable compensation, and of the level of transparency in this area. • Monitoring of objectives for gender balance on executive bodies, and more generally on Sanofi's diversity policy. • Monitoring of the Company's equal pay and equal opportunity policy. • Monitoring of the Planet Mobilization program, and review of Sanofi's climate commitments.

In addition, two strategy seminars were held, in March and October 2021, in which all members of the Executive Committee took part. The seminar gave directors an opportunity to address issues including:

- progress on the Play to Win strategy;
- changes to our R&D strategy;
- update on the situation in General Medicines;
- update on the strategy and growth trajectory for Vaccines;
- growth for Dupixent® and opportunities for Specialty Care, especially in oncology;
- update on the delivery of our digital strategy, and our digital ambitions;
- update on our development pipeline; and
- our financial roadmap.

Activities of the Board Committees in 2021

Since 1999, our Board of Directors has been assisted in its deliberations and decisions by specialist Committees (for a description of the remit of each Committee, refer to our Board Charter, provided as Exhibit 1.2 to this Annual Report on Form 20-F). Chairs and members of these Committees are chosen by the Board from among its members, based on their experience.

The Committees are responsible for the preparation of certain items on the agenda of the Board of Directors. Decisions of the Committees are adopted by a simple majority with the Chair of the Committee having a casting vote. Minutes are drafted, and approved by the Committee members.

The Chair of each Committee reports to the Board on the work of that Committee, so that the Board is fully informed whenever it takes a decision.

Composition of the committees during the 2021 financial year:

Audit Committee

	Composition as of January 1, 2021	Composition as of December 31, 2021
Chair	Fabienne Lecorvaisier (independent director)	Fabienne Lecorvaisier (independent director)
Members	Gilles Schnepp (independent director) Diane Souza (independent director) Christophe Babule	Diane Souza (independent director) Christophe Babule
	Proportion of independent directors: 75% (3/4)	**Proportion of independent directors: 66% (2/3)**

Appointments, Governance and CSR Committee

	Composition as of January 1, 2021	Composition as of December 31, 2021
Chair	Serge Weinberg (independent director)	Gilles Schnepp[(a)] (independent director)
Members	Patrick Kron (independent director) Melanie Lee (independent director)	Serge Weinberg [(b)] Patrick Kron (independent director) Melanie Lee (independent director) Lise Kingo[(c)] (independent director)
	Proportion of independent directors: 100% (3/3)	**Proportion of independent directors: 80% (4/5)**

(a) Gilles Schnepp was appointed chairman of the Appointments, Governance and CSR Committee by decision of the Board of Directors on December 15, 2021.

(b) Serge Weinberg is no longer regarded as independent since December 2021.

(c) Lise Kingo was appointed a member of the Appointments, Governance and CSR Committee by decision of the Board of Directors on April 30, 2021.

Compensation Committee

	Composition as of January 1, 2021	Composition as of December 31, 2021
Chair	Patrick Kron (independent director)	Patrick Kron (independent director)
Members	Carole Piwnica (independent director) Diane Souza (independent director)	Carole Piwnica (independent director) Diane Souza (independent director) Rachel Duan[(a)] (independent director)
	Proportion of independent directors: 100% (3/3)	**Proportion of independent directors: 100% (4/4)**

(a) Rachel Duan was appointed a member of the Appointments, Governance and CSR Committee by decision of the Board of Directors on April 30, 2021.

Strategy Committee

	Composition as of January 1, 2021	Composition as of December 31, 2021
Chair	Serge Weinberg (independent director)	Serge Weinberg
Members	Paul Hudson Laurent Attal Patrick Kron (independent director)	Paul Hudson Patrick Kron (independent director) Gilles Schnepp[(a)] (independent director)
	Proportion of independent directors: 50% (2/4)	**Proportion of independent directors: 50% (2/4)**

(a) Gilles Schnepp was appointed a member of the Strategy Committee by decision of the Board of Directors on April 30, 2021.

Scientific Committee

	Composition as of January 1, 2021	Composition as of December 31, 2021
Chair	Thomas Südhof (independent director)	Thomas Südhof (independent director)
Members	Laurent Attal Melanie Lee (independent director) Serge Weinberg (independent director)	Melanie Lee (independent director) Serge Weinberg
	Proportion of independent directors: 75% (3/4)	**Proportion of independent directors: 66% (2/3)**

Audit Committee

Two of the three members of the Audit Committee (Fabienne Lecorvaisier and Diane Souza) qualify as independent pursuant to the criteria adopted by the Board of Directors. All three members have financial or accounting expertise as a consequence of their training and professional experience, and all are deemed to be financial experts as defined by the Sarbanes-Oxley Act and by Article L. 823-19 of the French Commercial Code. See "Item 16A. Audit Committee Financial Expert".

The Audit Committee met six times in 2021, including prior to the meetings of the Board of Directors during which the financial statements were approved. In addition to the statutory auditors, the principal financial officers, the Senior Vice President Group Internal Audit and other members of the senior management team attended meetings of the Audit Committee, in particular when risk exposure and off-balance-sheet commitments were discussed.

The Committee members had an exemplary attendance record, with all members having an attendance rate of 100%.

The statutory auditors attend all meetings of the Audit Committee; they presented their opinions on the annual and half-year financial statements at the Committee meetings of February 2 and July 26, 2021, respectively. The Committee meets regularly with the statutory auditors without management present.

The Chairman of the Committee also meets regularly with certain members of management, in particular the heads of Internal Audit, Risk Management and Ethics/Compliance.

The internal procedures implemented by the Company for the identification and control of financial risks including off-balance sheet commitments as well as for the assessment of significant risks are detailed in the management report, see section "3.1.10. Internal control and risk management".

In 2021, the main activities of the Audit Committee related to:

Financial position	• Preliminary review of the individual company and consolidated financial statements for the 2020 financial year, review of the individual company and consolidated financial statements for the first half of 2021, review of the consolidated financial statements for the first three quarters of 2021, and review of draft press releases and presentations to analysts relating to the publication of those financial statements; • Sanofi's financial position, indebtedness and liquidity.
Internal audit, internal control and risk management	• Review of the work of the Internal Control function and evaluation of that work for 2020 as certified by the statutory auditors pursuant to Section 404 of the Sarbanes-Oxley Act, and examination of the 2020 Annual Report on Form 20-F. • Principal risks (risk management and risk profiles) facing Sanofi; Risk Committee report; review of whistleblowing and material compliance investigations; review of tax risks and deferred tax assets, and changes in tax legislation; review of material litigation. • Conclusions of Sanofi senior management on internal control procedures and review of the Board of Directors' 2020 Management Report, and in particular the description of risk factors contained in the French-language *Document d'enregistrement universel* and the Annual Report on Form 20-F for 2020. • Update on cyber-security and data protection. • Analysis of the external assessment conducted in 2021 on risk management. • Internal audit report for 2020 (including self-assessment), and audit program for 2021. • Update on crisis management and business continuity. • Impairment testing of goodwill, update on pension plans and actuarial assumptions. • Reporting on guarantees. • Review of application of the internal charter on related-party agreements.
Strategy and compensation	• Update on intellectual property strategy. • Update on supply chain continuity. • Presentation of the 2022 budget. • Assessment of fulfilment of the performance conditions of the 2018 equity-based compensation plans. • Scrutiny of draft resolutions on delegations of financial authority. • Update on the proposed initial public offering of EUROAPI.
Compliance, ethics and business integrity, and CSR	• Update on the data protection compliance program. • Presentation on ethics and business integrity within Sanofi. • Pharmaceutical residues in the environment.
Relations with the statutory auditors	• Statutory audit engagement and audit fees. • Budget for non-audit services (audit-related services, tax, and other services). • Update on the renewal of statutory auditor appointments.

The Committee did not use external consultants in 2021

Compensation Committee

All four members of the Compensation Committee are deemed to be independent.

The Compensation Committee met three times in 2021, with an overall attendance rate of 100%.

When the Committee discusses the compensation policy for members of senior management who are not corporate officers, i.e. the members of the Executive Committee, the Committee invites the Chief Executive Officer to attend.

In 2021, the main activities of the Compensation Committee related to:

Compensation of corporate officers	• Components of the compensation of corporate officers (Chief Executive Officer and Chairman of the Board). • Review of performance criteria applicable to the compensation of the Chief Executive Officer, in particular CSR criteria. • Allocation of the amount of directors' compensation for 2020, and review of the compensation policy applicable to directors (discusssions about compensation for meetings held by videoconference). • Review of the disclosures about compensation contained in the corporate governance section of the 2020 French-language *Document d'enregistrement universel* and the Annual Report on Form 20-F, and of equal pay ratios. • Review of the draft resolutions to be submitted to the Annual General Meeting of April 30, 2021. • Governance roadshow campaign arranged for the main investors in Sanofi, and an analysis of the policies adopted by proxy advisors.
Equity-based compensation	• Review of the equity-based compensation policy consisting of performance shares, including a review of the TSR criterion. • Implementation of share-based compensation plans awarded in previous years (level of attainment of performance conditions for 2018 plans and the Phantom Stock Unit plan awarded to Paul Hudson). • Status report on awards of performance shares, and proposal for off-cycle awards.
Employee share ownership plan	• Final figures and analysis of 2021 employee share ownership plan. • Planning for the next employee share ownership plan, and implementation of the Action 2022 Plan.
Compensation of Executive Committee members	• Monitoring of the fixed and variable remuneration of Executive Committee members in 2020 and 2021. • Information on terms for the hiring or departure of Executive Committee members.

The Committee used external consultants in 2021.

Appointments, Governance and CSR Committee

Among the five members of the Committee, four are deemed to be independent.

The Committee met five times in 2021, with an overall attendance rate of 100%.

In 2021, the main activities of the Appointments, Governance and CSR Committee related to:

Appointments	• Succession planning for the Chairman and the Chief Executive Officer. • Changes in the composition of the Board and its Committees. • Changes to the Executive Committee in line with the Play to Win strategy. • Proposed reappointments of directors, and appointments of new directors.
Corporate governance	• Summary of the 2020 Board evaluation (conducted under the direction of the Committee), and implementation of the 2021 formal evaluation of the work of the Board and its Committees. • Review of director independence. • Review of the Management Report and the corporate governance section of the 2020 French-language *Document d'enregistrement universel* and the Annual Report on Form 20-F. • The governance roadshow campaign arranged for the main investors in Sanofi, and an analysis of the policies adopted by proxy advisors. • Proposed amendments of the Articles of Association pursuant to the entry into force of the Pacte law. • Revisions to the Board Charter.
Corporate and Social Responsability Matters	• Monitoring of changes in gender balance within executive bodies. • Review of the CSR policy of Sanofi and its principal competitors, and consideration of new orientations, specifically the commitment to showing leadership in health care.

The Committee used external consultants in 2021.

Strategy Committee

Two of the four members of the Strategy Committee are deemed to be independent: Patrick Kron and Gilles Schnepp.

The Strategy Committee met five times in 2021.

The Committee members had an exemplary attendance record, with an overall attendance rate of 100%.

In 2021, the main activities of the Strategy Committee related to:

- update on China;
- divestment and acquisition proposals, and business development priorities;
- delivery on the Play to Win strategy; and
- opportunities for alliances.

The Committee did not use external consultants in 2021.

Scientific Committee

Two of the three members of the Scientific Committee are independent, and its main roles are:

- to assist the Board in scrutinizing the strategic orientation and investments proposed by senior management from a scientific standpoint;
- to identify and discuss emerging trends and new challenges in science and technology, and ensure that Sanofi is as well prepared as possible to meet those challenges;
- to ensure that processes are in place to enable optimal decision-making on investments in R&D, consistent with the strategy determined by the Board; and
- to review and evaluate the quality of Sanofi's scientific expertise, and advise the Board accordingly.

The Committee met three times in 2021, with all of its members present (100% attendance rate) along with the Chief Executive Officer, global support function managers and other Sanofi employees.

The main activities of the Committee in 2021 related to:

- update on the use of digital in R&D;
- macro-molecule research; and
- cell and gene therapy.

The Committee did not use external consultants in 2021.

Attendance rate of Board members

Director	Attendance rate at Board meetings	Attendance rate at Committee meetings	Overall attendance rate
Serge Weinberg, Chairman of the Board	100%	100%	100%
Paul Hudson, Chief Executive Officer	100%	100%	100%
Laurent Attal[(a)]	100%	100%	100%
Christophe Babule	100%	100%	100%
Bernard Charlès[(a)]	75%	—	75%
Rachel Duan	100%	100% [(c)]	100%
Lise Kingo	100%	100% [(d)]	100%
Patrick Kron	100%	100%	100%
Wolfgang Laux[(b)]	100%	—	100%
Barbara Lavernos[(b)]	100%	—	100%
Fabienne Lecorvaisier	100%	100%	100%
Melanie Lee	100%	100%	100%
Marion Palme[(a)]	—	—	—
Carole Piwnica	100%	100%	100%
Christian Senectaire[(a)]	100%	—	100%
Gilles Schnepp	100%	100% [(b)]	100%
Diane Souza	100%	100%	100%
Thomas Südhof	100%	100%	100%
Yann Tran[(b)]	100%	—	100%

Average attendance rate at Board and Committee meetings	Average attendance rate at Board meetings	Average attendance rate at Committee meetings
99%	98%	100%

(a) Laurent Attal, Bernard Charlès, Marion Palme and Christian Senectaire all left the Board during 2021.
(b) Barbara Lavernos, Wolfgang Laux and Yann Tran joined the Board during 2021.
(c) Rachel Duan joined the Compensation Committee in April 2021 and attended both of the meetings held after her appointment.
(d) Lise Kingo joined the Appointments, Governance and CSR Committee in April 2021 and attended both of the meetings meetings held after her appointment.

Directors who were absent from some meetings provided clear and substantiated explanations for their absence, which related mainly to personal matters or to unscheduled meetings called at short notice (especially where sudden developments on an ongoing project necessitated a Board meeting).

D. Employees

Number of Employees

In 2021, Sanofi employed 95,442 people worldwide, 3,970 fewer than in 2020. The tables below give a breakdown of employees by geographical area and function as of December 31, 2021, 2020 and 2019.

Employees by Geographical Area

	As of December 31,					
	2021	%	2020	%	2019	%
Europe	47,039	49.3%	46,761	47.0%	46,236	46.0%
United States	13,030	13.7%	12,972	13%	12,592	12.5%
Rest of the World	35,373	37.1 %	39,679	39.9%	41,581	41.4%
Total	**95,442**	**100.0%**	**99,412**	**100.0%**	**100,409**	**100.0%**

Employees by Function

	As of December 31,			
	2021	2020	2019	2018
Sales Force	21,113	25,203	26,178	28,914
Research and Development	16,223	15,446	15,538	15,140
Production	37,431	37,935	37,873	38,790
Marketing and Support Functions	20,675	20,828	20,820	21,382
Total	**95,442**	**99,412**	**100,409**	**104,226**

Industrial Relations

In all countries where we operate, we seek to strike a balance between our economic interests and those of our employees, which we regard as inseparable.

Our responsibility towards our employees is based on the basic principles of our Social Charter, which outlines the rights and duties of all Sanofi employees. The Social Charter addresses our key commitments towards our workforce: equal opportunity for all people without discrimination, the right to health and safety, respect for privacy, the right to information and professional training, social protection for employees and their families, freedom of association and the right to collective bargaining, and respect for the principles contained in the Global Compact on labor relations and ILO conventions governing the physical and emotional well-being and safety of children.

Our labor relations are based on respect and dialogue. In this spirit, management and employee representatives meet regularly to exchange views, negotiate, sign agreements and ensure that agreements are being implemented.

Employee dialogue takes place in different ways from country to country, as dictated by specific local circumstances. Depending on the circumstances, employee dialogue relating to information, consultation and negotiation processes may take place at national, regional or company level. It may be organized on an interprofessional or sectorial basis, or both. Employee dialogue may be informal or implemented through a specific formal body, or a combination of both methods. Whatever the situation, Sanofi encourages employees to voice their opinions, help create a stimulating work environment and take part in decisions aiming to improve the way we work. These efforts reflect one of the principles of the Social Charter, whereby improving working conditions and the necessary adaptation to our business environment go hand-in-hand.

Profit-sharing Schemes, Employee Savings Schemes and Employee Share Ownership

Profit-sharing schemes

All employees of our French companies belong to voluntary and statutory profit-sharing schemes.

Voluntary schemes

Voluntary schemes *(intéressement des salariés)* are collective schemes that are optional for the employer and contingent upon performance. The aim is to give employees an interest in the growth of the business and improvements in its performance.

Sanofi did not distribute any profit-sharing in 2021 under voluntary schemes in respect of the 2020 financial year, as the special profit-sharing reserve exceeded the maximum amount, as determined by application of the criteria defined by the profit-sharing agreement.

In April 2020, we entered into a new fixed-term statutory profit-sharing agreement for the 2020, 2021 and 2022 financial years, which applies to all employees of our French companies. Under the agreement, Sanofi pays collective variable compensation determined on the basis of the more favorable of (i) growth in consolidated net sales (at constant exchange rates and on a constant structure basis) or (ii) the ratio of our business operating income to net sales, expressed as a percentage (BOI margin). For each of those criteria, a matrix determines what percentage of total payroll is to be allocated to the scheme. An additional sum may be distributed, based on a CSR-related performance condition reflecting progress in environmental matters (reduction in greenhouse gas emissions) and capped at 0.5% of total payroll.

This overall allocation is reduced by the amount required by law to be transferred to a special profit-sharing reserve. The balance is then distributed between the employees unless the transfer to the reserve equals or exceeds the maximum amount determined under the specified criteria, in which case no profit share is paid to the employees.

Statutory scheme

The statutory scheme (*participation des salariés aux résultats de l'entreprise*) is a French legal obligation for companies with more than 50 employees that made a profit in the previous financial year.

The amount distributed by our French companies during 2021 in respect of the statutory scheme for the year ended December 31, 2020 represented 10.37% of total payroll.

Distribution formula

In order to favor lower-paid employees, the voluntary and statutory profit-sharing agreements entered into since 2005 split the benefit between those entitled as follows:

- 60% prorated on the basis of time spent in the Company's employment in the year; and
- 40% prorated on the basis of gross annual salary received during the year, subject to a lower limit equal to the social security ceiling and an upper limit of three times the social security ceiling.

Employee savings schemes and collective retirement savings plan

The employee savings arrangements operated by Sanofi are based on a collective savings scheme *(Plan d'Épargne Groupe)* and a collective retirement savings scheme *(Plan d'Épargne pour la Retraite Collectif)*. Those schemes reinvest the sums derived from the statutory and voluntary profit-sharing schemes, plus voluntary contributions from employees.

In June 2021, 93.17% of the employees who benefited from the profit-sharing schemes opted to invest in the collective savings scheme, and nearly 82.3% opted to invest in the collective retirement savings scheme.

Sanofi supplements the amount invested by employees in these schemes by making a top-up contribution.

In 2021, €134 million and €62.3 million were invested in the collective savings scheme and the collective retirement savings scheme respectively through the voluntary and statutory schemes for 2020, and through top-up contributions.

Employee share ownership

As of December 31, 2021, shares held under the collective savings scheme by employees of Sanofi, employees of related companies and former employees amounted to 1.90% of our share capital.

For more information about our most recent employee share ownership plan, refer to "Item 10. Additional Information — Changes in Share Capital — Increases in Share Capital".

E. Share Ownership

Senior Management

Members of the Executive Committee hold shares of our Company amounting in the aggregate to less than 1% of our share capital.

Existing Option Plans as of December 31, 2021

In 2019, the Board of Directors reviewed Sanofi's compensation policy and decided that stock options would no longer be awarded from 2020 onwards. That decision was taken to standardize the terms of equity-based compensation awards within Sanofi, and in response to feedback from some shareholders and proxy advisors who had concerns about stock options given their dilutive effect and potential unintended consequences.

Share Purchase Option Plans

As of December 31, 2021 there were no stock purchase option plans outstanding.

Share Subscription Option Plans

Source	Date of shareholder authorization	Date of grant	Total number of options granted	to corporate officers[a]	to the 10 employees awarded the most options[b]	Start date of exercise period	Expiry date	Exercise price (€)	Number of shares subscribed as of 12/31/2021	Number of options canceled as of 12/31/2021[c]	Number of options outstanding
Sanofi-aventis	April 17, 2009	March 9, 2011	574,500	—	395,000	March 10, 2015	March 9, 2021	50.48	539,036	35,464	—
Sanofi-aventis	April 17, 2009	March 9, 2011	300,000	300,000	—	March 10, 2015	March 9, 2021	50.48	292,200	7,800	—
Sanofi	May 6, 2011	March 5, 2012	574,050	—	274,500	March 6, 2016	March 5, 2022	56.44	414,159	95,943	63,948
Sanofi	May 6, 2011	March 5, 2012	240,000	240,000	—	March 6, 2016	March 5, 2022	56.44	204,720	35,280	—
Sanofi	May 6, 2011	March 5, 2013	548,725	—	261,000	March 6, 2017	March 5, 2023	72.19	260,350	109,065	179,310
Sanofi	May 6, 2011	March 5, 2013	240,000	240,000	—	March 6, 2017	March 5, 2023	72.19	—	64,080	175,920
Sanofi	May 3, 2013	March 5, 2014	769,250	—	364,500	March 6, 2018	March 5, 2024	73.48	248,393	102,625	418,232
Sanofi	May 3, 2013	March 5, 2014	240,000	240,000	—	March 6, 2018	March 5, 2024	73.48	—	46,560	193,440
Sanofi	May 3, 2013	June 24, 2015	12,500	—	12,500	June 25, 2019	June 24, 2025	89.38	—	8,500	4,000
Sanofi	May 3, 2013	June 24, 2015	202,500	—	202,500	June 25, 2019	June 24, 2025	89.38	45,000	—	157,500
Sanofi	May 3, 2013	June 24, 2015	220,000	220,000	—	June 25, 2019	June 24, 2025	89.38	—	41,536	178,464
Sanofi	May 4, 2016	May 4, 2016	17,750	—	17,750	May 5, 2020	May 4, 2026	75.90	—	9,750	8,000
Sanofi	May 4, 2016	May 4, 2016	165,000	—	165,000	May 5, 2020	May 4, 2026	75.90	67,600	—	97,400
Sanofi	May 4, 2016	May 4, 2016	220,000	220,000	—	May 5, 2020	May 4, 2026	75.90	—	41,250	178,750
Sanofi	May 10, 2017	May 10, 2017	158,040	—	157,140	May 11, 2021	May 10, 2027	88.97	—	41,250	116,790
Sanofi	May 10, 2017	May 10, 2017	220,000	220,000	—	May 11, 2021	May 10, 2027	88.97	—	42,570	177,430
Sanofi	May 2, 2018	May 2, 2018	220,000	220,000	—	May 3, 2022	May 2, 2028	65.84	—	51,216	168,784
Sanofi	April 30, 2019	April 30, 2019	220,000	220,000	—	May 2, 2023	April 30, 2029	76.71	—	—	220,000

(a) Comprises the Chief Executive Officer, and any Deputy Chief Executive Officers or members of the Management Board in office at the date of grant.
(b) In office at the date of grant.
(c) Includes 338,996 options cancelled due to partial non-fulfilment of performance conditions.

In 2021, 9,363 stock options were exercised by individuals who were Executive Committee members as of December 31, 2021. All of the plans involved post-date the creation of the Executive Committee: Sanofi-Aventis plan of March 9, 2011, exercise price €50.48; Sanofi plan of March 5, 2012, exercise price €56.44; and Sanofi plan of March 5, 2013, exercise price €72.19.

As of December 31, 2021, a total of 2,337,968 stock subscription options remained outstanding. As of the same date, 1,949,184 options were immediately exercisable.

Existing Performance Share Plans as of December 31, 2021

The Board of Directors awards shares to certain employees in order to give them a direct stake in our future and performances via trends in the share price, as a partial substitute for the granting of stock options.

Shares are awarded to employees by the Board of Directors on the basis of a list submitted to the Compensation Committee. The Board of Directors sets terms of the awards, including continuing employment conditions and performance conditions (measured over three financial years).

The employee plans have a three-year vesting period, with no lock-up period.

At its meeting of April 30, 2021, the Board of Directors awarded a share performance plan, cascaded down into five sub-plans:

- a France plan under which 201 beneficiaries classified as “Senior Executives” were awarded a total of 497,695 shares;
- a France plan under which 1,869 beneficiaries not classified as “Senior Executives” were awarded a total of 595,878 shares;
- an International plan under which 248 beneficiaries classified as “Senior Executives” were awarded a total of 701,824 shares;
- an International plan under which 4,217 beneficiaries classified as “Senior Executives” were awarded a total of 1,614,023 shares; and
- a plan under which 75,000 performance shares were awarded to the Chief Executive Officer.

Of the 6,536 beneficiaries, 46% were women.

At its meeting of October 27, 2021, the Board of Directors awarded a share performance plan under which five beneficiaries classified as "Senior Executives" were awarded a total of 13,521 shares.

Of those five beneficiaries, 60% were women.

The entirety of those awards is contingent upon criteria based on business net income (BNI) and free cash flow (FCF); in the case of employees classified as "Senior Executives", an additional criterion based on total shareholder return (TSR) is added, accounting for 20% of the total. Vesting is subject to a non-compete clause.

The number of shares awarded to the Chief Executive Officer in 2021 represents 0.4% of the total limit approved by our shareholders at the Annual General Meeting of April 30, 2021 (1.5% of our share capital) and 2.14% of the total amount awarded to all beneficiaries.

The 2021 awards represent a dilution of approximately 0.28% of our undiluted share capital as of December 31, 2021.

Not all of our employees were awarded performance shares, but a new voluntary profit-sharing agreement was signed in April 2020 which gives all of our employees an interest in Sanofi's performance (for more details refer to "— Profit-Sharing Schemes, Employee Savings Schemes and Employee Share Ownership", above).

Performance Share Plans

Source	Date of shareholder authorization	Date of award	Total number of shares awarded	to corporate officers[a]	to the 10 employees awarded the most shares[b]	Start date of vesting period[c]	Vesting date	End of lock-up period	Number of shares vested as of 12/31/2021	Number of rights canceled as of 12/31/2021[d]	Number of shares not yet vested
Sanofi	May 4, 2016	May 2, 2018	1,513,074	—	144,372	May 2, 2018	May 3, 2021	May 3, 2021	1,379,866	133,208	—
Sanofi	May 4, 2016	May 2, 2018	2,827,142	—	272,447	May 2, 2018	May 3, 2021	May 3, 2021	2,122,012	705,130	—
Sanofi	May 4, 2016	May 2, 2018	50,000	50,000	—	May 2, 2018	May 3, 2021	May 3, 2021	38,360	11,640	—
Sanofi	May 4, 2016	July 30, 2018	141,669	—	39,874	July 30, 2018	July 31, 2021	July 31, 2021	84,533	57,136	—
Sanofi	April 30, 2019	April 30, 2019	50,000	50,000	—	April 30, 2019	May 1, 2022	May 2, 2022	—	—	50,000
Sanofi	April 30, 2019	April 30, 2019	1,243,434	—	142,541	April 30, 2019	May 1, 2022	May 2, 2022	326	56,500	1,186,608
Sanofi	April 30, 2019	April 30, 2019	2,504,148	—	219,990	April 30, 2019	May 1, 2022	May 2, 2022	—	612,298	1,891,850
Sanofi	April 30, 2019	April 28, 2020	75,000	75,000	—	April 28, 2020	May 1, 2023	May 2, 2023	—	—	75,000
Sanofi	April 30, 2019	April 28, 2020	328,113	—	120,951	April 28, 2020	May 1, 2023	May 2, 2023	0	34,222	293,891
Sanofi	April 30, 2019	April 28, 2020	400,495	—	151,761	April 28, 2020	May 1, 2023	May 2, 2023	—	78,425	322,070
Sanofi	April 30, 2019	April 28, 2020	753,720	—	19,027	April 28, 2020	May 1, 2023	May 2, 2023	—	15,322	738,398
Sanofi	April 30, 2019	April 28, 2020	1,783,173	—	26,542	April 28, 2020	May 1, 2023	May 2, 2023	—	265,185	1,517,988
Sanofi	April 30, 2019	October 28, 2020	73,027	—	73,027	October 28, 2020	October 29, 2023	October 30, 2023	—	5,878	67,149
Sanofi	April 30, 2021	April 30, 2021	1,614,023	—	19,407	April 30, 2021	May 1, 2024	May 1, 2024	—	95,461	1,518,562
Sanofi	April 30, 2021	April 30, 2021	701,824	—	163,877	April 30, 2021	May 1, 2024	May 1, 2024	—	25,860	675,964
Sanofi	April 30, 2021	April 30, 2021	595,878	—	10,918	April 30, 2021	May 1, 2024	May 1, 2024	—	3,715	592,163
Sanofi	April 30, 2021	April 30, 2021	497,695	—	150,339	April 30, 2021	May 1, 2024	May 1, 2024	—	8,010	489,685
Sanofi	April 30, 2021	April 30, 2021	75,000	75,000	—	April 30, 2021	May 1, 2024	May 1, 2024	—	—	75,000
Sanofi	April 30, 2021	October 27, 2021	13,521	—	13,521	October 27, 2021	October 28, 2024	October 28, 2024	—	—	13,521

(a) Comprises the Chairman & Chief Executive Officer, the Chief Executive Officer, and any Deputy Chief Executive Officers or members of the Management Board in office at the date of grant.
(b) In office at the date of grant.
(c) Subject to the conditions set.
(d) Includes 702,543 rights cancelled due to partial non-fulfilment of performance conditions.

As of December 31, 2021, 9,507,849 shares had not yet vested pending fulfilment of performance conditions.

In the interests of transparency, we disclose below attainment levels (as determined by our Board of Directors) and allocation rates for the performance conditions applicable to the equity-based compensation plans awarded to our Chief Executive Officer and the other members of our Executive Committee. The Board believes that disclosing those attainment levels gives our shareholders a better understanding of the demanding nature of those conditions.

During the year ended December 31, 2021, the ten employees (other than corporate officers) awarded the most shares were collectively awarded a total of 233,857 shares.

Shares Owned by Members of the Board of Directors

As of December 31, 2021, members of our Board of Directors held in the aggregate 22,334 shares, or under 1% of the share capital and of the voting rights, excluding the beneficial ownership of 118,227,307 shares held by L'Oréal as of such date which may be attributed to Barbara Lavernos or Christophe Babule (who disclaim beneficial ownership of such shares).

Transactions in Shares by Members of the Board of Directors and Equivalent Persons in 2021

As far as Sanofi is aware, transactions in our securities carried out during 2021 by (i) Board members, (ii) executives with the power to make management decisions affecting our future development and corporate strategy and (iii) persons with close personal ties to such individuals (as per Article L. 621-18-2 of the French Monetary and Financial Code), were as follows:

- on December 22, 2021, Barbara Lavernos (director) purchased 500 shares at a price of €87.70 per share.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The table below shows the ownership of our shares as of January 31, 2022, indicating the beneficial owners of our shares. To the best of our knowledge and on the basis of the notifications received as disclosed below, except for L'Oréal and BlackRock, Inc., no other shareholder currently holds more than 5% of our share capital or voting rights.

	Total number of issued shares		Number of actual voting rights (excluding treasury shares)[(d)]		Theoretical number of voting rights (including treasury shares)[(e)]	
	Number	%	Number	%	Number	%
L'Oréal	118,227,307	9.36	236,454,614	16.83	236,454,614	16.65
BlackRock[(a)]	88,988,906	7.04	88,988,906	6.33	88,988,906	6.27
Employees[(b)]	23,433,679	1.85	42,754,194	3.04	42,754,194	3.01
Public	1,017,968,003	80.56	1,037,095,137	73.80	1,037,095,137	73.01
Treasury shares[(c)]	14,994,953	1.19	—	—	14,994,953	1.06
Total	**1,263,612,848**	**100**	**1,405,292,851**	**100**	**1,420,287,804**	**100**

(a) Based on BlackRock's declaration dated January 28, 2022.
(b) Shares held via the Sanofi Group Employee Savings Plan.
(c) Number of shares repurchased as of January 31, 2022 under the share repurchase program in force.
(d) Based on the total number of voting rights as of January 31, 2022.
(e) Based on the total number of voting rights as of January 31, 2022 as published in accordance with article 223-11 and seq. of the General Regulations of the Autorité des marchés financiers (i.e. including treasury shares, the voting rights of which are suspended).

Our Articles of Association provide for double voting rights for shares held in registered form for at least two years. All of our shareholders may benefit from double voting rights if these conditions are met, and no shareholder benefits from specific voting rights. For more information relating to our shares, see "Item 10. Additional Information — B. Memorandum and Articles of Association."

Neither L'Oréal nor BlackRock holds different voting rights from those of our other shareholders.

To the best of our knowledge, no other shareholder currently holds, directly or indirectly and acting alone or in concert, more than 5% of our share capital or voting rights. Furthermore, we believe that we are not directly or indirectly owned or controlled by another corporation or government, or by any other natural or legal persons. To our knowledge, there are no arrangements that may result in a change of control.

During the year ended December 31, 2021 we received several share ownership declarations informing us that a legal threshold had been passed, as required under Article L. 233-7 of the French Commercial Code.

Dodge & Cox, acting on behalf of its clients and funds under its management, declared that on August 11, 2021 it had passed above the 5% threshold in terms of share capital, and holds, on behalf of its clients and funds, 5.01% of the share capital and 4.48% of the voting rights.

Dodge & Cox, acting on behalf of its clients and funds under its management, declared that on November 8, 2021 it had passed above the 5% threshold in terms of voting rights, and holds, on behalf of its clients and funds, 5.63% of the share capital and 5.00% of the voting rights.

Dodge & Cox, acting on behalf of its clients and funds under its management, declared that on November 12, 2021 it had passed below the 5% threshold in terms of voting rights, and holds, on behalf of its clients and funds, 5.61% of the share capital and 4.99% of the voting rights.

In addition to the statutory requirement to inform the Company and the *Autorité des marchés financiers* (AMF, the French Financial Markets Regulator) that they hold a number of shares (or of securities equivalent to shares or of voting rights pursuant to Article L. 233-9 of the French Commercial Code) representing more than one-twentieth (5%), one-tenth (10%), three-twentieths (15%), one-fifth (20%), one-quarter (25%), three-tenths (30%), one-third (1/3), one-half (50%), two-thirds (2/3), nine-tenths (90%) or nineteen-twentieths (95%) of the share capital or theoretical voting rights within four trading days after crossing any such ownership threshold (Article L. 233-7 of the French Commercial Code), any natural or legal person who directly or indirectly comes to hold a percentage of the share capital, voting rights or securities giving future access to the Company's capital that is equal to or greater than 1% or any multiple of that percentage, is obliged to inform the Company thereof by registered mail, return receipt requested, indicating the number of securities held, within five trading days following the date on which each of the thresholds was crossed.

If such declaration is not made, the shares in excess of the fraction that should have been declared will be stripped of voting rights at shareholders' meetings, if on the occasion of such meeting, the failure to declare has been formally noted and one or more shareholders collectively holding at least 5% of the Company's share capital or voting rights so request at that meeting.

Any natural or legal person is also required to inform the Company, in the forms and within the time limits stipulated above for passing above a specified threshold, if their direct or indirect holding passes below any of the aforementioned thresholds.

Since January 1, 2022 Sanofi has only received share ownership declarations of statutory threshold.

As of December 31, 2021, individual shareholders (including employees of Sanofi and its subsidiaries, as well as retired employees holding shares via the Sanofi Group Employee Savings Plan) held approximately 7.27% of our share capital. Institutional shareholders (excluding L'Oréal) held approximately 77.67% of our share capital. Such shareholders are primarily American (31.93%), French (12.76%) and British (13.34%). German institutions held 4.37% of our share capital, Swiss institutions held 2.19%, institutions from other European countries held 2.12% and Canadian institutions held 1.43% of our share capital. Other international institutional investors (excluding those from Europe and North America) held approximately 1.13% of our share capital. In France, our home country, we have 11,462 identified shareholders of record. In the United States, our host country, we have 48 identified shareholders of record and 18,068 identified ADS holders of record.

(Source: a survey conducted by Euroclear France as of December 31, 2021, and internal information).

Shareholders' Agreement

We are unaware of any shareholders' agreement currently in force.

B. Related Party Transactions

See Note D.33. to our consolidated financial statements included at Item 18. of this annual report.

C. Interests of Experts and Counsel

N/A

Item 8. Financial Information

A. Consolidated Financial Statements and Other Financial Information

Our consolidated financial statements as of and for the years ended December 31, 2021, 2020 and 2019 are included in this annual report at "Item 18. Financial Statements."

Dividends on Ordinary Shares

We paid annual dividends for the years ended December 31, 2017, 2018, 2019 and 2020 and our shareholders will be asked to approve the payment of an annual dividend of 3.33 per share for the 2021 fiscal year at our next annual shareholders' meeting. If approved, this dividend will be paid on May 10, 2022.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2021 dividend equates to a distribution of 50.8% of our business net income. For information on the non-GAAP financial measure "business earnings per share" see "Item 5. Operating and Financial Review and Prospects — Business Net Income."

The following table sets forth information with respect to the dividends paid by our Company in respect of the 2017, 2018, 2019 and 2020 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the 2021 fiscal year at our May 3, 2022 shareholders' meeting.

	2021 [(a)]	2020	2019	2018	2017
Dividend per Share (€)	3.33	3.2	3.15	3.07	2.96
Dividend per Share ($)[(b)]	3.91	3.53	3.52	3.63	3.12

(a) Proposal, subject to shareholder approval.
(b) Based on the relevant year-end exchange rate.

The declaration, amount and payment of any future dividends will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our Board of Directors. Any declaration will depend on our results of operations, financial condition, cash requirements, future prospects and other factors deemed relevant by our shareholders. Accordingly, we cannot assure you that we will pay dividends in the future on a continuous and regular basis. Under French law, we are required to pay dividends approved by an ordinary general meeting of shareholders within nine months following the meeting at which they are approved.

Disclosure pursuant to Section 13(r) of the United States Exchange Act of 1934

Sanofi engages in limited business activities with Iran related to human health products – namely, sales of bulk and branded pharmaceuticals and vaccines . These activities, which are disclosed pursuant to Section 13(r) of the United States Exchange Act of 1934, as amended, are not financially material to Sanofi and contributed well under 1% of Sanofi's consolidated net sales in 2021.

Sanofi's US affiliates and non-US affiliates owned or controlled by Sanofi's US affiliates either do not engage in Iran-related activities or act under licenses issued by the US Department of the Treasury's Office of Foreign Assets Control (OFAC).

Sanofi and certain non-US Sanofi affiliates engage in limited business activities that neither are expressly authorized by OFAC nor require such authorization.

In 2016, Sanofi and the Iran Food and Drug Administration (IFDA), an entity affiliated with the Iranian Ministry of Health and Medical Education, signed a Memorandum of Cooperation (MOC) regarding: (i) potential future projects to reinforce current partnerships with reputable Iranian manufacturers (in particular, to enhance industrial quality standards); (ii) collaborating with the Ministry of Health and Medical Education on programs for the prevention and control of certain chronic and non-communicable diseases (in particular, diabetes); and (iii) potential future collaboration on epidemiological studies. In 2021, activities conducted under the MOC did not generate any revenue or net profits.

Certain non-US Sanofi affiliates engage in limited business with Iranian counterparties associated with the Iranian Ministry of Health, such as public hospitals or distributors. In 2021, those business activities generated approximately €14.5 million in gross revenue and contributed no more than €3 million in net profits.

Finally, a representative office in Tehran incurs incidental expenses from state-owned utilities.

Sanofi believes that it and its affiliates' activities are compliant with applicable law, and in light of the nature of the activities concerned, Sanofi and its affiliates intend to continue their ongoing activities in Iran.

Information on Legal or Arbitration Proceedings

This Item 8. incorporates by reference the disclosures found in Note D.22. to the consolidated financial statements at Item 18. of this annual report; material updates thereto as of the date of this annual report are found below under the heading "— B. Significant Changes — Updates to Note D.22.".

Sanofi and its subsidiaries are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of Sanofi products), competition law and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures.

As a result, we may become subject to substantial liabilities that may not be covered by insurance and could affect our business and reputation. While we do not currently believe that any of these legal proceedings will have a material adverse effect on our financial position, litigation is inherently unpredictable. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on results of operations, cash flows and/or our reputation.

Patents

Lantus® Mylan Patent Litigation (United States)

In June 2017, Mylan Pharmaceuticals, Inc. filed petitions for *Inter Partes* Review (IPR) for US Patent Nos. 7,476,652 and 7,713,930 regarding Lantus® with the United States Patent Office Patent Trial and Appeal Board (PTAB). In these petitions, Mylan attacks the validity of all claims of these patents. In December 2018, the PTAB issued a decision invalidating the claims of the two formulation patents. In November 2019, a panel of three judges of the United States Court of Appeals for the Federal Circuit issued a divided public ruling affirming the December 2018 PTAB decisions invalidating the Lantus® formulation patents. In October 2020, the Supreme Court declined review of the November 2019 Federal Circuit ruling. In November 2020, the District of New Jersey entered final judgment of invalidity on these formulation patents. The proceedings concerning the formulation patents are now closed.

In October 2017, several Sanofi entities filed a patent infringement suit against Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharmaceuticals Inc. (collectively, "Mylan") in the United States District Courts for the District of New Jersey and Northern District of West Virginia. In its suits, Sanofi alleges infringement of several patents. The suits were triggered by a notification received from Mylan in mid-September 2017, in which Mylan stated that it had filed an 505(b)(2) NDA with the FDA for insulin glargine drug pen and vial products. Mylan also stated that its NDA included a paragraph IV certification challenging all of the Sanofi patents then listed in the FDA Orange Book for Sanofi's Lantus® and Lantus® SoloSTAR® products. In February 2018, the West Virginia case was dismissed and the parties proceeded only with the New Jersey lawsuit. Biocon Ltd., Biocon Research Ltd., Biocon SDN.BHD., and Biocon S.A., were added to the New Jersey lawsuit in July 2018. In March 2020, the New Jersey District Court ruled in Mylan's favor, finding the asserted claims of US Patent No. 9,526,844 invalid and not infringed by Mylan's pen product. Sanofi has appealed to the US Court of Appeals for the Federal Circuit (CAFC). On December 29, 2021, the CAFC affirmed the PTAB's invalidity rulings (see below) and, as a result, dismissed this appeal as moot. Mylan had launched its non-interchangeable pen and vial products in August 2020.

In September 2018, Mylan filed 10 petitions asking the PTAB to commence IPR proceedings of US Patent Nos. 8,603,044, 8,679,069, 8,992,486, 9,526,844, and 9,604,008, challenging the validity of certain claims of these Sanofi patents. The PTAB decided to move forward with nine of the 10 IPR proceedings concerning these five patents. Pfizer Inc. joined eight of these nine IPRs, and filed a separate IPR concerning US Patent No. 8,679,069. In 2020, the PTAB ruled that two claims of US 9,604,008 are valid and that the rest of the challenged claims are invalid. Sanofi has appealed the adverse PTAB decisions to the CAFC, and Mylan and Pfizer have cross-appealed the decision that was adverse to them. In January 2021, Sanofi settled with Pfizer concerning its involvement in these matters. In May 2021, Mylan's cross appeal concerning US Patent No. 9,604,008 was dismissed by the CAFC. On December 29, 2021, the CAFC affirmed the PTAB's invalidity rulings.

In October 2019, Mylan filed two petitions asking the PTAB to commence IPR proceedings of US Patent No. RE47 614, challenging the validity of the claims of this Sanofi patent. The PTAB decided to move forward and examine the validity of the claims of this patent in one of these two IPRs in April 2020. In March 2021, the PTAB issued a written decision invalidating all claims of this patent. In May 2021, Sanofi appealed to the CAFC. The appeal is underway.

• *Cerdelga® Patent Litigation (United States)*

In March 2021, Sanofi-Genzyme settled the case with all of the defendants (Cipla Limited; Zenara Pharma Private Limited; Teva Pharmaceuticals USA, Inc.; Dr. Reddy's Laboratories, Ltd.; Apotex Inc.; Aizant Drug Research Solutions Private Limited). The case is closed.

Government investigations and related litigation

From time to time, subsidiaries of Sanofi are subject to governmental investigations and information requests from regulatory authorities inquiring as to the practices of Sanofi with respect to the sales, marketing, and promotion of its products.

In June 2016, the United States declined to intervene in a False Claims Act action filed in Federal Court in New Jersey claiming that Sanofi did not disclose certain variability of response to Plavix®. The relator continued their case and it was dismissed in May 2019. The Third Circuit Court of Appeals reversed the dismissal in September 2020 and remanded to the trial court in New Jersey for further proceedings. The case was dismissed a second time in October 2021. A second appeal is expected. Sanofi US is also defending a State Attorney General action in New Mexico state court concerning the sale and marketing of Plavix®. Trial has been set for April 2022.

From 2017 through 2020, several government agencies issued Civil Investigative Demands (CIDs) or other discovery requests calling for the production of documents and information relating to Sanofi's trade and pricing practices for its insulin products and/or Lantus®-related litigation. Sanofi US is cooperating with each of the following investigations, none of which has been closed:

- Washington State Attorney General's office (CID issued in March 2017, covering the period from 2005 to the present);
- California State Attorney General's office (issued first set of interrogatories in April 2018 covering the period from 2009 to the present; document requests in February 2020, covering the period from 2014 to the present; investigative examination subpoena in June 2020, covering the period 2014 to the present; and second set of interrogatories in September 2020, covering the period from 2014 to the present);
- New York State Attorney General's office (document subpoena issued in July 2019, covering the period from 2013 to the present);
- Colorado State Attorney General's office (CID issued in December 2019, covering the period from 2010 to the present); and
- Vermont State Attorney General's office (CID issued in December 2020, covering the period from 2011 to the present).

In September 2019, Sanofi US received a Civil Investigative Demand (CID) from the US Department of Justice concerning Dupixent®, Kevzara®, Praluent® and Zaltrap®. In June 2021, the government declined to intervene in the underlying complaint which was filed in

November 2018. The government investigation into this matter is now closed. Relators, however, filed their First Amended Complaint in October 2021 and Defendants filed motions to dismiss in January 2022.

In February 2020, Genzyme Corporation received a CID from the US Department of Justice. The CID requests documents and information relating to Genzyme Corporation's payments made to vendors or developers of electronic health record technology. Genzyme Corporation is cooperating with this investigation.

Insulin Related Litigation

In December 2016 and January 2017, two putative class actions were filed against Sanofi US and Sanofi GmbH in the US Federal Court in Massachusetts on behalf of direct purchasers of Lantus® alleging certain antitrust violations. In January 2018, the Court dismissed Plaintiffs' complaint against Sanofi. Plaintiffs appealed that order to the Court of Appeals for the First Circuit, which issued its decision on February 13, 2020 reversing and remanding to the district court. Discovery is underway.

There are several litigation matters pending in the United States that have been filed against Sanofi US (and two other insulin manufacturers) regarding, as concerns Sanofi US, the pricing of Lantus®, Apidra®, and Toujeo®. The suits allege some combination of: violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO Act"); violations of various state unfair/deceptive trade practices statutes, violations of federal antitrust laws, unjust enrichment, common-law fraud, and civil conspiracy. The status of these matters is as follows:

- *In re Insulin Pricing* (Federal District Court of New Jersey, filed in 2017 on behalf of a putative class of diabetes patients):
  - discovery commenced in September 2019;
- *MSP Recovery Claims, Series LLC v. Sanofi-Aventis US LLC. et al.* (Federal District Court of New Jersey, filed in 2018 on behalf of Medicare Secondary Payors):
  - discovery commenced in November 2020;
- *State of Minnesota vs. Sanofi US et al.* (Federal District Court of New Jersey, filed in 2018):
  - discovery commenced in July 2020;
- *Commonwealth of Kentucky vs. Sanofi-Aventis US LLC. et al.* (Kentucky State Court, filed in 2019):
  - court denied the defendants' motion to dismiss in January 2020; Discovery has yet to commence;
- *Harris County, Texas vs. Sanofi-Aventis US LLC. et al.* (Federal Southern District Court of Texas, filed in 2019):
  - the defendants are the three insulin manufacturers as well as the top three Pharmacy Benefit Managers (PBMs) and related entities,
  - discovery commenced in April 2021;
- *In re Direct Purchaser Insulin Pricing Litigation* (Federal District Court of New Jersey, filed in 2020 by FWK Holdings, LLC and Professional Drug Company on behalf of a putative class of direct purchasers of insulin):
  - the defendants are the three insulin manufacturers and the top three Pharmacy Benefit Managers (PBMs) and related entities,
  - discovery commenced in December 2021;
- *Mississippi vs. Eli Lilly & Co. et al.* (Federal Northern District Court of Mississippi, filed in June 2021):
  - the defendants are the three insulin manufacturers and the top three PBMs and related entities;
  - the parties are briefing the defendants' motion to dismiss;
- *Miami, Florida vs. Eli Lilly & Co. et al.* (Federal Southern District Court of Florida, filed in June 2021):
  - the defendants are the three insulin manufacturers and the top three PBMs and related entities;
  - the defendants' motion to dismiss is pending.

B. Significant Changes

Updates to Note D.22.

Plavix® (clopidogrel)-related litigation in France

On February 9, 2022, the Paris Court of Appeals overturned the Paris Commercial Court's ruling, finding the *French Caisse Nationale d'Assurance Maladie - CNAM* (French Social Security)'s action as not time-barred and designated an expert to determine the amount of damages.

Taxotere® Product Litigation in the US

On February 11, 2022, the US Court of Appeals, 5th Circuit, remanded the first bellwether case for a new trial due to improper evidence being admitted.

Other Changes

On January 7, 2022, Sanofi and Exscientia announced a research collaboration and license agreement to develop up to 15 novel small molecule candidates across oncology and immunology, leveraging Exscientia's end-to-end AI-driven platform utilizing actual patient samples. The companies have been working together since 2016 and in 2019, Sanofi in-licensed Exscientia's novel bispecific small molecule candidate capable of targeting two distinct targets in inflammation and immunology. Under the terms of the agreement, Exscientia will receive an upfront cash payment of $100 million from Sanofi and will be eligible to receive future research, translational,

clinical development, regulatory and commercial milestone payments of up to approximately $5.2 billion in aggregate, if all milestones for all programs are achieved. In the event that Sanofi commercializes a therapeutic product from the collaboration, Exscientia will also be eligible to receive tiered royalties on product sales ranging from high-single-digits to mid-teens and an option for clinical co-investment to increase the royalty rate up to 21% on net sales of co-funded products.

On January 19, 2022, a second Phase III trial evaluating Dupixent® (dupilumab) in adults with uncontrolled prurigo nodularis, a chronic type 2 inflammatory skin disease, met its primary and key secondary endpoints, showing it significantly reduced itch and skin lesions compared to placebo at 24 weeks in this investigational setting. The data confirm the positive results that were previously reported from the Phase III PRIME2 trial and will be submitted to regulatory authorities around the world starting in the first half of this year.

On January 31, 2022, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending extension of the approval of Dupixent® (dupilumab) in the European Union (EU) to include add-on maintenance treatment for children aged 6 to 11 years with severe asthma with type 2 inflammation characterized by raised blood eosinophils and/or raised fractional exhaled nitric oxide (FeNO) who are inadequately controlled on two maintenance therapies. The European Commission is expected to announce a final decision on the Dupixent® application in the coming months after the date of this annual report.

On February 3, 2022, Sanofi unveiled a new corporate branding to support the modernization of the Company launched in December 2019.

On February 4, 2022, the US Food and Drug Administration (FDA) approved Enjaymo™ (sutimlimab-jome) to decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease (CAD). Enjaymo™ is the first and only approved treatment for people with CAD and works by inhibiting the destruction of red blood cells (hemolysis).

On February 8, 2022, Sanofi announced the completion of its acquisition of Amunix Pharmaceuticals, Inc, adding a promising pipeline of T-cell engagers and cytokine therapies. The acquisition also provides access to Amunix Pro-XTEN™, XPAT, and XPAC technology to deliver next generation Conditionally Activated Biologics. The technology platform is highly complementary to Sanofi's existing R&D platforms and supports Sanofi's efforts to accelerate and expand its contributions to innovative medicines for oncology patients, with approximately 20 molecules currently in development.

On February 10, 2022, the US Food and Drug Administration (FDA) accepted for Priority Review the supplemental Biologics License Application (sBLA) for Dupixent® (dupilumab) as an add-on maintenance treatment for children aged 6 months to 5 years with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. The target action date for the FDA decision on this investigational use is June 9, 2022. Dupixent® remains the only biologic medicine approved for patients 6 years of age and older for this indication.

On February 18, 2022, Sanofi announced that a Phase 3 trial (CUPID STUDY B) evaluating Dupixent® (dupilumab) in patients with chronic spontaneous urticaria (CSU), who were refractory to omalizumab, will stop due to futility based on a pre-specified interim analysis. Although positive numerical trends in reducing itch and hives were observed, the results from the interim analysis did not demonstrate statistical significance for the primary endpoints. The analysis was conducted by an independent interim analysis review committee. In the trial, patients who were refractory to omalizumab treatment and uncontrolled on antihistamines received Dupixent® plus standard of care compared to standard of care alone for 24 weeks. The safety data were generally consistent with the known safety profile of Dupixent® in its approved indications. The LIBERTY-CUPID pivotal program was initiated in 2020 with an accelerated direct-to-Phase 3 strategy. The previously reported Phase 3 trial, which evaluated a different group of patients who were biologic-naïve, met its primary and all key secondary endpoints at 24 weeks showing that adding Dupixent® to standard-of-care antihistamines significantly reduced itch and hives compared to antihistamines alone. The companies remain committed to advancing Dupixent® for patients with CSU uncontrolled on antihistamines and are evaluating next steps.

On February 23, 2022, Sanofi and GSK announced that they intend to submit data from both their booster and Phase 3 efficacy trials as the basis for regulatory applications for a COVID-19 vaccine.

The public health relevance of the refrigerator temperature-stable adjuvanted protein-based Sanofi-GSK vaccine is strongly supported by the induction of robust immune responses and a favorable safety profile in multiple settings. In participants who had received a primary series of an already authorized mRNA or adenovirus vaccine, the Sanofi-GSK booster vaccine induced a significant increase in neutralizing antibodies of 18- to 30-fold across vaccine platforms and age groups. When the Sanofi-GSK vaccine was used as a two-dose primary series followed by a booster dose, neutralizing antibodies increased 84- to 153-fold compared to pre-boost levels.

- Final analysis of the global VAT02 booster trial confirms universal ability to boost neutralizing antibodies 18- to 30-fold across vaccine platforms (mRNA, adenovirus)
- In the VAT08 Phase 3 primary series trial, two doses of the Sanofi-GSK vaccine in seronegative populations demonstrated:
    - 100% efficacy against severe COVID-19 disease and hospitalizations
    - 75% efficacy against moderate or severe COVID-19 disease
    - 57.9% efficacy against any symptomatic COVID-19 disease, in line with expected vaccine effectiveness in today's environment dominated by variants of concern
- Favorable safety profile following both primary series and booster vaccinations

Item 9. The Offer and Listing

A. Offer and Listing Details

We have one class of shares. Each American Depositary Share, or ADS, represents one-half of one share. The ADSs are evidenced by American Depositary Receipts, or ADRs, which are issued by JPMorgan Chase Bank, N.A.

Our shares trade on Compartment A of the regulated market of Euronext Paris, and our ADSs trade on the Nasdaq Global Select Market, or Nasdaq.

B. Plan of Distribution

N/A

C. Markets

Shares and ADSs

Our shares are listed on Euronext Paris under the symbol “SAN” and our ADSs are listed on the Nasdaq under the symbol “SNY”.

As of the date of this annual report, our shares are included in a large number of indices, including the “CAC 40 Index”, the principal French index published by Euronext Paris. This index contains 40 stocks selected among the top 100 companies based on free-float capitalization and the most active stocks listed on the Euronext Paris market. The CAC 40 Index indicates trends in the French stock market as a whole and is one of the most widely followed stock price indices in France. Our shares are also included in the S&P Global 100 Index, the Dow Jones Euro STOXX 50, the FTS Eurofirst 300, the MSCI Euro Index and the NASDAQ Composite Index among other multi-sectorial and sectorial indices. Our shares are also part of the main extra-financial rating indices (Dow Jones Sustainability Index World, the FTSE4Good, ATM index or Stoxx® Global ESG Leaders).

Trading by Sanofi in our own Shares

Under French law, a company may not issue shares to itself, but it may purchase its own shares in the limited cases described at “Item 10. Additional Information — B. Memorandum and Articles of Association — Trading in Our Own Shares.”

D. Selling Shareholders

N/A

E. Dilution

N/A

F. Expenses of the Issue

N/A

Item 10. Additional Information

A. Share Capital

N/A

B. Memorandum and Articles of Association

General

Our Company is a *société anonyme*, a form of limited liability company, organized under the laws of France. The LEI number of the Company is 549300E9PC51EN656011.

In this section, we summarize material information concerning our share capital, together with material provisions of applicable French law and our Articles of Association (*statuts*), an English translation of which has been filed as an exhibit to this annual report. For a description of certain provisions of our Articles of Association relating to our Board of Directors and statutory auditors, see "Item 6. Directors, Senior Management and Employees". You may obtain copies of our Articles of Association in French from the *greffe* (Clerk) of the *Registre du Commerce et des Sociétés de Paris* (Registry of Commerce and Companies of Paris, France, registration number: 395 030 844). Please refer to that full document for additional details.

Our Articles of Association specify that our corporate affairs are governed by:

- applicable laws and regulations (in particular, Title II of the French Commercial Code); and
- the Articles of Association themselves.

Article 3 of our Articles of Association specifies that the Company's corporate purpose, in France and abroad, is:

- acquiring interests and holdings, in any form whatsoever, in any company or enterprise, in existence or to be created, connected directly or indirectly with the health and fine chemistry sectors, human and animal therapeutics, nutrition and bio-industry;

  in the following areas:

  – purchase and sale of all raw materials and products necessary for these activities,
  – research, study and development of new products, techniques and processes,
  – manufacture and sale of all chemical, biological, dietary and hygienic products,
  – obtaining or acquiring all intellectual property rights related to results obtained and, in particular, filing all patents, trademarks and models, processes or inventions,
  – operating directly or indirectly, purchasing, and transferring – for free or for consideration – pledging or securing all intellectual property rights, particularly all patents, trademarks and models, processes or inventions,
  – obtaining, operating, holding and granting all licenses,
  – within the framework of a group-wide policy and subject to compliance with the relevant legislation, participating in treasury management transactions, whether as lead company or otherwise, in the form of centralized currency risk management or intra-group netting, or any other form permitted under the relevant laws and regulations,

  and, more generally:

  – all commercial, industrial, real or personal property, financial or other transactions, connected directly or indirectly, totally or partially, with the activities described above and with all similar or related activities and even with any other purposes likely to encourage or develop the Company's activities.

Directors

Transactions in which directors are materially interested

Under French law, any agreement entered into (directly or through an intermediary) between our Company and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our business and (ii) under normal conditions, is subject to the prior authorization of the disinterested members of the Board of Directors. The same provision applies to agreements between our Company and another company if one of the members of the Board of Directors is the owner, general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the members of the Board of Directors has an indirect interest.

The Board of Directors must also approve any undertaking taken by our Company for the benefit of our Chairman, Chief Executive Officer *(directeur général)* or his delegates *(directeurs généraux délégués)* pursuant to which such persons will or may be granted compensation, benefits or any other advantages as a result of the termination of or a change in their offices or following such termination or change, in accordance with Article L. 22-10-8 of the French Commercial Code. Each such undertaking must be included in our compensation policy for corporate officers, which is submitted for approval by our shareholders at the Annual General Meeting in accordance with Article L. 22-10-8 II of the French Commercial Code. No such compensation or undertaking may be determined, awarded or paid unless in accordance with such compensation policy. See "Item 6. Directors, Senior Management and Employees — B. Compensation" for a description of the process for establishing and authorizing such compensation policy.

Directors' compensation

The aggregate amount of compensation of the Board of Directors is determined at the Shareholders' Ordinary General Meeting. The Board of Directors then divides this aggregate amount among its members by a simple majority vote. In addition, the Board of Directors may grant exceptional compensation *(rémunérations exceptionnelles)* to individual directors on a case-by-case basis for special assignments following the procedures described above at "— Transactions in which directors are materially Interested". The Board of Directors may also authorize the reimbursement of travel and accommodation expenses, as well as other expenses incurred by Directors in the corporate interest. See also "Item 6. Directors, Senior Management and Employees."

Board of Directors' borrowing powers

All loans or borrowings on behalf of the Company may be decided by the Board of Directors within the limits, if any, imposed by the Shareholders' Extraordinary General Meeting. There are currently no limits imposed on the amounts of loans or borrowings that the Board of Directors may approve.

Directors' age limits

For a description of the provisions of our Articles of Association relating to age limits applicable to our Directors, see "Item 6. Directors, Senior Management and Employees".

Directors' share ownership requirements

Pursuant to the Board Charter, our Directors must within no more than two years from their appointment hold at least 1,000 Sanofi shares in their own name, which must be retained until they cease to hold office.

Share capital

As of December 31, 2021, our share capital amounted to €2,527,121,390, divided into 1,263,560,695 outstanding shares with a par value of €2 per share. All of our outstanding shares are of the same class and are fully paid. Of these shares, we or entities controlled by us held 11,017,961 shares (or 0.87% of our outstanding share capital), as treasury shares as of such date. As of December 31, 2021, the carrying amount of such shares was €694 million.

At a combined general meeting held on April 30, 2021, our shareholders authorized our Board of Directors to increase our share capital, through the issuance of shares or other securities giving access to the share capital with or without preemptive rights, by an aggregate maximum nominal amount of €997 million. See "— Changes in Share Capital — Increases in Share Capital", below.

The maximum total number of authorized but unissued shares as of December 31, 2021 was 131.85 million, reflecting the unused part of the April 30, 2021 shareholder authorizations to issue shares without preemptive rights, outstanding options to subscribe for shares, and awards of shares.

Stock options

Types of stock options

We have two types of stock options outstanding: options to subscribe for shares *(options de souscription d'actions)* and options to purchase shares *(options d'achat d'actions)*. Upon exercise of an option to subscribe for shares, we issue new shares, whereas upon exercise of an option to purchase shares, the option holder receives existing shares. We purchase our shares on the market prior to the vesting of the options to purchase in order to provide the option holder with shares upon exercise.

Because the exercise of options to purchase shares will be satisfied with existing shares repurchased on the market or held in treasury, the exercise of options to purchase shares has no impact on the amount of our share capital.

Stock option plans

Our combined general meeting held on April 30, 2019 authorized our Board of Directors for a period of 38 months, i.e. effective until July 30, 2022, to grant, on one or more occasions, options to subscribe for shares and options to purchase shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or groupings of economic interest of the Group in accordance with Article L. 225-180 of the French Commercial Code.

The aggregate number of options to subscribe for shares and options to purchase shares that may be granted under this authorization may not give entitlement to a total number of shares exceeding 0.5% of the share capital as of the date of the decision by the Board of Directors to grant such options.

The Board of Directors sets the exercise price of options to subscribe for shares and options to purchase shares. However, the exercise price never incorporates a discount and must be at least equal (i) in the case of a grant of options to subscribe for shares, to the average of the quoted market prices of Sanofi's shares on the 20 trading sessions preceding the date of grant by the Board of Directors and (ii) in the case of a grant of options to purchase shares, either (a) the price indicated in (i) or (b) the average purchase price of shares held by Sanofi under Articles L. 225-208 and L. 225-209 of the French Commercial Code.

Stock option plans generally provide for a lock-up period of four years and have a duration of ten years.

Under such authorization the shareholders expressly waive, in favor of the grantees of options to subscribe for shares, their preemptive rights in respect of shares that are to be issued as and when options are exercised.

The Board of Directors is granted full power to implement this authorization and to set the terms and conditions on which options are granted and the arrangements with respect to the dividend entitlement of the shares.

With effect from June 2019, the Chief Executive Officer can only be awarded performance shares. As a result, in 2021 the Board of Directors did not grant any stock-options.

See “Item 6. Directors, Senior Management and Employees — E. Share Ownership” for a description of our option plans currently in force.

Awards of shares

Our combined general meeting held on April 30, 2021 authorized our Board of Directors for a period of 38 months to allot, on one or more occasions, existing or new restricted shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or economic interest groupings of the Group in accordance with Articles L. 225-197-1 et seq. of the French Commercial Code.

The existing or new shares allotted under this authorization may not represent more than 1.5% of our share capital as of the date of the decision by the Board of Directors to allot such shares.

The authorization provides that allotment of shares to the allottees will become irrevocable at the end of a minimum vesting period of three years.

In the case of newly issued shares, the authorization entails the express waiver by the shareholders, in favor of the allottees of restricted shares, of their preemptive rights in respect of shares that are to be issued as and when restricted shares vest.

The Board of Directors sets the terms on which restricted shares are granted and the arrangements with respect to the dividend entitlement of the shares.

See “Item 6. Directors, Senior Management and Employees — E. Share Ownership” for a description of our restricted shares plans currently in force.

Changes in share capital in 2021

See Note D.15.1. to our consolidated financial statements, included at Item 18. of this annual report.

Voting rights

In general, each shareholder is entitled to one vote per share at any shareholders’ general meeting. Our Articles of Association do not provide for cumulative voting rights. However, our Articles of Association provide that any fully paid-up shares that have been held in registered form under the name of the same shareholder for at least two years acquire double voting rights. The double voting rights cease automatically for any share converted into bearer form or transferred from one owner to another, subject to certain exceptions permitted by law.

As of December 31, 2021, there were 156,721,583 shares that were entitled to double voting rights, representing 12.40% of our total share capital, and approximately 11.12% of the voting rights which can be cast at our shareholders’ general meeting as of that date.

Double voting rights are not taken into account in determining whether a quorum exists.

Under the French Commercial Code, treasury shares or shares held by entities controlled by that company are not entitled to voting rights and do not count for quorum purposes.

Our Articles of Association allow us to obtain from Euroclear France the name, nationality, address and number of shares held by holders of our securities that have, or may in the future have, voting rights. If we have reason to believe that a person on any list provided by Euroclear France holds securities on behalf of another person, our Articles of Association allow us to request information regarding beneficial ownership directly from such person. See “— B. Memorandum and Articles of Association — Form, Holding and Transfer of Shares”, below.

Our Articles of Association provide that Board members are elected on a rolling basis for a maximum tenure of four years.

Shareholders’ agreement

We are not aware of any shareholder’s agreement currently in force concerning our shares.

Shareholders’ meetings

General

In accordance with the provisions of the French Commercial Code, there are three types of shareholders’ meetings: ordinary, extraordinary and special.

Ordinary general meetings of shareholders are required for matters such as:

- electing, replacing and removing Directors;
- appointing independent auditors;
- approving the annual financial statements;
- declaring dividends or authorizing dividends to be paid in shares, provided the Articles of Association contain a provision to that effect; and
- approving share repurchase programs.

Extraordinary general meetings of shareholders are required for approval of matters such as amendments to our Articles of Association, including any amendment required in connection with extraordinary corporate actions. Extraordinary corporate actions include:

- changing our Company’s name or corporate purpose;
- increasing or decreasing our share capital;
- creating a new class of equity securities;

- authorizing the issuance of:
  - shares giving access to our share capital or giving the right to receive debt instruments, or
  - other securities giving access to our share capital;
- establishing any other rights to equity securities;
- selling or transferring substantially all of our assets; and
- the voluntary liquidation of our Company.

Special meetings of shareholders of a certain category of shares or shares with certain specific rights (such as shares with double voting rights) are required for any modification of the rights derived from that category of shares. The resolutions of the shareholders' general meeting affecting these rights are effective only after approval by the relevant special meeting.

Annual ordinary meetings

The French Commercial Code requires the Board of Directors to convene an annual ordinary general shareholders' meeting to approve the annual financial statements. This meeting must be held within six months of the end of each fiscal year.

The Board of Directors may also convene an ordinary or extraordinary general shareholders' meeting upon proper notice at any time during the year. If the Board of Directors fails to convene a shareholders' meeting, our independent auditors may call the meeting. In case of bankruptcy, the liquidator or court-appointed agent may also call a shareholders' meeting in some instances. In addition, any of the following may request the court to appoint an agent for the purpose of calling a shareholders' meeting:

- one or several shareholders holding at least 5% of our share capital;
- duly qualified associations of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights;
- the works council in cases of urgency; or
- any interested party in cases of urgency.

Under our Articles of Association, the Board of Directors may take decisions by written consultation under the conditions permitted by law and as specified in the Board Charter (an English language version of which is reproduced in full as Exhibit 1.2 to this Annual Report on Form 20-F), including the possibility to convene an ordinary or extraordinary general meeting,

Notice of shareholders' meetings

All prior notice periods provided for below are minimum periods required by French law and cannot be shortened, except in case of a public tender offer for our shares.

We must announce general meetings at least thirty-five days in advance by means of a preliminary notice *(avis de réunion)*, which is published in the *Bulletin des Annonces Légales Obligatoires*, or *BALO*. The preliminary notice must first be sent to the French Financial markets authority (*Autorité des marchés financiers*, the "AMF"), with an indication of the date on which it will be published in the *BALO*. It must be published on our website at least twenty-one days prior to the general meeting. The preliminary notice must contain, among other things, the agenda, a draft of the resolutions to be submitted to the shareholders for consideration at the general meeting and a detailed description of the voting procedures (proxy voting, electronic voting or voting by mail), the procedures permitting shareholders to submit additional resolutions or items to the agenda and to ask written questions to the Board of Directors. The AMF also recommends that, prior to or simultaneously with the publication of the preliminary notice, we publish a summary of the notice indicating the date, time and place of the meeting in a newspaper of national circulation in France and on our website.

At least fifteen days prior to the date set for a first convening, and at least ten days prior to any second convening, we must send a final notice *(avis de convocation)* containing the final agenda, the date, time and place of the meeting and other information related to the meeting. Such final notice must be sent by mail to all registered shareholders who have held shares in registered form for more than one month prior to the date of the final notice and by registered mail, if shareholders have asked for it and paid the corresponding charges. The final notice must also be published in a newspaper authorized to publish legal announcements in the local administrative department *(département)* in which our Company is registered as well as in the *BALO*, with prior notice having been given to the AMF for informational purposes. Even if there are no proposals for new resolutions or items to be submitted to the shareholders at the meeting, we must publish a final notice in a newspaper authorized to publish legal announcements in the local administrative department *(département)* in which our Company is registered as well as in the *BALO*.

Other issues

In general, shareholders can only take action at shareholders' meetings on matters listed on the agenda. As an exception to this rule, shareholders may take action with respect to the appointment and dismissal of directors even if this action has not been included on the agenda.

Additional resolutions to be submitted for approval by the shareholders at the shareholders' meeting may be proposed to the Board of Directors, for recommendation to the shareholders at any time from the publication of the preliminary notice in the *BALO* until twenty-five days prior to the general meeting and in any case no later than twenty days following the publication of the preliminary notice in the *BALO* by:

- one or several shareholders together holding a specified percentage of shares;
- a duly qualified association of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights; or
- the works council.

Within the same period, the shareholders may also propose additional items (*points*) to be submitted and discussed during the shareholders' meeting, without a shareholders' vote. The shareholders must substantiate the reasons for their proposals of additional items.

The resolutions and the list of items added to the agenda of the shareholders' meeting must be promptly published on our website.

The Board of Directors must submit the resolutions to a vote of the shareholders after having made a recommendation thereon. The Board of Directors may also comment on the items that are submitted to the shareholders' meeting.

Following the date on which documents must be made available to the shareholders (including documents to be submitted to the shareholders' meeting and resolutions proposed by the Board of Directors, which must be published on our website at least twenty-one days prior to the general meeting), shareholders may submit written questions to the Board of Directors relating to the agenda for the meeting until the fourth business day prior to the general meeting. The Board of Directors must respond to these questions during the meeting or may refer to a Q&A section located on our website in which the question submitted by a shareholder has already been answered.

Attendance at shareholders' meetings; proxies and votes by mail

In general, all shareholders may participate in general meetings either in person or by proxy. Shareholders may vote in person, by proxy or by mail.

The right of shareholders to participate in general meetings is subject to the recording *(inscription en compte)* of their shares on the second business day, 0.0 a.m. (Paris time), preceding the general meeting:

- for holders of registered shares: in the registered shareholder account held by the Company or on its behalf by an agent appointed by it; and
- for holders of bearer shares: in the bearer shareholder account held by the accredited financial intermediary with whom such holders have deposited their shares; such financial intermediaries shall deliver to holders of bearer shares a shareholding certificate *(attestation de participation)* enabling them to participate in the general meeting.

Attendance in person

Any shareholder may attend ordinary general meetings and extraordinary general meetings and exercise its voting rights subject to the conditions specified in the French Commercial Code, the French Civil Code and our Articles of Association.

An attendance sheet and written minutes are established for each shareholders' meeting; failure to do so could lead to cancellation of the decisions at the shareholders' meeting.

Proxies and votes by mail

Proxies are sent to any shareholder upon a request received between the publication of the final notice of meeting and six days before the general meeting and must be made available on our website at least twenty-one days before the general meeting. In order to be counted, such proxies must be received at our registered office, or at any other address indicated on the notice of the meeting or by any electronic mail indicated on the notice of the meeting, prior to the date of the meeting (in practice, we request that shareholders return proxies at least three business days prior to the meeting; electronic proxies must be returned before 3 p.m. Paris time, on the day prior to the general meeting). A shareholder may grant proxies to any natural person or legal entity. The agent may be required to disclose certain information to the shareholder or to the public.

A proxy is only valid for one meeting (or by way of exception for two meetings, one being ordinary and the other extraordinary, held on the same day or within a single 15-day period); it remains valid in the event such meeting is convened multiple times for the same agenda, and may be revoked by written statement of the shareholder granting the proxy.

Alternatively, the shareholder may send us a blank proxy without nominating any representative. In this case, the chairman of the meeting will vote the blank proxies in favor of all resolutions proposed or approved by the Board of Directors and against all others.

With respect to votes by mail, we must send shareholders a voting form upon request or must make available a voting form on our website at least twenty-one days before the general meeting. The completed form must be returned to us at least three days prior to the date of the shareholders' meeting. For holders of registered shares, in addition to traditional voting by mail, instructions may also be given via the internet.

Quorum

The French Commercial Code requires that shareholders holding in the aggregate at least 20% of the shares entitled to vote must be present in person, or vote by mail or by proxy, in order to fulfill the quorum requirement for:

- an ordinary general meeting; and
- an extraordinary general meeting where the only resolutions pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (Article L. 233-32 of the French Commercial Code).

For any other extraordinary general meeting the quorum requirement is at least 25% of the shares entitled to vote, held by shareholders present in person, voting by mail or by proxy.

For a special meeting of holders of a certain category of shares, the quorum requirement is one third of the shares entitled to vote in that category, held by shareholders present in person, voting by mail or by proxy.

If a quorum is not present at a meeting, the meeting is adjourned. However, only questions that were on the agenda of the adjourned meeting may be discussed and voted upon once the meeting resumes.

When an adjourned meeting is resumed, there is no quorum requirement for meetings cited in the first paragraph of this "Quorum" section. In the case of any other reconvened extraordinary general meeting or special meeting, the quorum requirement is 20% of the shares entitled to vote (or voting shares belonging to the relevant category for special meetings of holders of shares of such specific category), held by shareholders present in person or voting by mail or by proxy. If a quorum is not met, the reconvened meeting may be adjourned for a maximum of two months with the same quorum requirement. No deliberation or action by the shareholders may take place without a quorum.

Votes required for shareholder action

The affirmative vote of a simple majority of the votes cast may pass a resolution at either an ordinary general meeting or an extraordinary general meeting where the only resolution(s) pertain(s) to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (Article L. 233-32 of the French Commercial Code). At any other extraordinary general shareholders' meeting and at any special meeting of holders of a specific category of shares, the affirmative vote of two-thirds of the votes cast by those present or those represented by proxy or voting by mail is required.

As a result of a recent change in French law, as of the Annual General Meeting of April 28, 2020, abstention from voting, blank votes and null votes by those present or those represented by proxy or voting by mail are no longer counted as votes against the resolution submitted to a shareholder vote at any of the three types of meetings.

Changes to shareholders' rights

Under French law, the affirmative vote of two-thirds of the votes cast at an extraordinary shareholders' meeting is required to change our Articles of Association, which set out the rights attached to our shares, except for capital increases through incorporation of reserves, profits or share premium, or through the issuance of free share warrants in the event of a public tender offer for our shares (Article L. 233-32 of the French Commercial Code).

The rights of a class of shareholders can be amended only after a special meeting of the class of shareholders affected has taken place. The voting requirements applicable to this type of special meeting are the same as those applicable to an extraordinary general shareholders' meeting. The quorum requirements for a special meeting are one-third of the voting shares, or 20% upon resumption of an adjourned meeting.

A unanimous shareholders' vote is required to increase the liabilities of shareholders.

Financial statements and other communications with shareholders

In connection with any shareholders' meeting, we must provide a set of documents which includes our annual report.

We must also provide on our website at least twenty-one days before a shareholders' meeting certain information and a set of documents that includes the preliminary notice, the proxies and voting forms, the resolutions proposed by the Board of Directors, and the documents to be submitted to the shareholders' meeting pursuant to Articles L. 225-115 and R. 225-83 of the French Commercial Code, etc. The resolutions and the list of items added to the agenda of the shareholders' meeting must be promptly published on our website.

Dividends

We may only distribute dividends out of our "distributable profits," plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law or our Articles of Association. "Distributable profits" consist of our unconsolidated net profit in each fiscal year, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to law or our Articles of Association.

Legal reserve

The French Commercial Code requires us to allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. This restriction on the payment of dividends also applies to each of our French subsidiaries on an unconsolidated basis. At December 31, 2021, our legal reserve amounted to €282,280,863.40, representing 11.21% of the aggregate par value of our issued and outstanding share capital as of that date. The legal reserve of any company subject to this requirement may serve to allocate losses that may not be allocated to other reserves, or may be distributed to shareholders upon liquidation of the company.

Approval of dividends

According to the French Commercial Code, our Board of Directors may propose a dividend for approval by shareholders at the annual general shareholders' meeting. If we have earned distributable profits since the end of the preceding fiscal year, as reflected in an interim income statement certified by our independent auditors, our Board of Directors may distribute interim dividends to the extent of the distributable profits for the period covered by the interim income statement. Our Board of Directors exercises this authority subject to French law and regulations and may do so without obtaining shareholder approval.

Distribution of dividends

Dividends are distributed to shareholders pro rata according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by our Board of Directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders' meeting or by our Board of Directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Dividends may be paid in cash or, if the shareholders' meeting so decides, in kind, provided that all shareholders receive a whole number of assets of the same nature paid in lieu of cash. Our Articles of Association provide that, subject to a decision of the shareholders' meeting taken by ordinary resolution, each shareholder may be given the choice to receive his dividend in cash or in shares.

Timing of payment

According to the French Commercial Code, we must pay any existing dividends within nine months of the end of our fiscal year, unless otherwise authorized by court order. Dividends on shares that are not claimed within five years of the date of declared payment revert to the French State.

Changes in share capital

Increases in share capital

As provided for by the French Commercial Code, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our Board of Directors. The shareholders may delegate to our Board of Directors either the authority *(délégation de compétence)* or the power *(délégation de pouvoir)* to carry out any increase in share capital. Our Board of Directors may further delegate this power to our Chief Executive Officer or, subject to our Chief Executive Officer's approval, to his delegates *(directeurs généraux délégués)*.

Increases in our share capital may be effected by:

- issuing additional shares;
- increasing the par value of existing shares;
- creating a new class of equity securities; or
- exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

- in consideration for cash;
- in consideration for assets contributed in kind;
- through an exchange offer;
- by conversion of previously issued debt instruments;
- by capitalization of profits, reserves or share premium; or
- subject to various conditions, in satisfaction of debt incurred by our Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium or through the issuance of free share warrants in the event of a public tender offer for our shares (Article L. 233-32 of the French Commercial Code) require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings. See "— Quorum" and "— Votes Required for Shareholder Action" above.

On April 30, 2021, our shareholders approved various resolutions delegating to the Board of Directors the authority to increase our share capital through the issuance of shares or securities giving access to the share capital, subject to an overall cap set at €997 million. This cap applies to all the resolutions whereby the extraordinary shareholders' meeting delegated to the Board of Directors the authority to increase the share capital, it being also specified that:

- the maximum aggregate par value of capital increases that may be carried out with preemptive rights maintained was set at €997 million;
- the maximum aggregate par value of capital increases that may be carried out by public offering (other than of the type specified in Article L. 411-2, 1° of the French Monetary and Financial Code) without preemptive rights was set at €240 million;
- the maximum aggregate par value of capital increases that may be carried out in connection with an offering of the type specified in Article L. 411-2, 1° of the French Monetary and Financial Code (i.e. an offer addressed exclusively to a limited number of investors) without preemptive rights was set at €240 million;
- capital increases resulting in the issuance of securities to members of employee savings plans are limited to 1% of the share capital as computed on the date of the Board of Directors' decision to issue such securities, and such issuances may be made at a discount of 30% (or 40%) if certain French law restrictions on resales were to apply, i.e. a lock up period of five years (or 10 years).

As of December 31, 2021, the shares held by the company's employees or by employees of affiliated companies, as well as former employees in the Group savings programs represented 1.90% of the share capital.

At its February 2021 meeting, our Board of Directors decided to delegate to the Chief Executive Officer the powers necessary to carry out a capital increase reserved for members of the Group savings program. Every employee subscribing for at least five shares received one additional new share as an employer's top-up contribution. Beyond the first twenty shares there was no entitlement to any further shares by way of employer's top-up contribution (every employee subscribing for twenty shares received four additional shares as an employer's top-up contribution). The subscription period was open during June 2021.

34,069 employees from nearly 71 countries subscribed for a total of 2,438,590 shares. Of these, 1,346,766 shares were subscribed via FCPE Actions Sanofi, the dedicated employee share ownership fund for employees of our French subsidiaries; 501,790 shares via FCPE Sanofi Shares, the dedicated employee share ownership fund for employees of our foreign subsidiaries; and 590,034 shares directly by

employees who were eligible for the employee share ownership plan but were in countries where local regulations did not allow the use of a dedicated employee share ownership fund.

A total of 124,112 shares were issued by way of employer's top-up contribution. Of these, 60,284 were issued to FCPE Actions Sanofi; 31,120 to FCPE Sanofi Shares; and 32,708 directly to employees who were eligible for the employee share ownership plan but were in countries where local regulations did not allow the use of a dedicated employee share ownership fund.

Voting rights attached to shares held by FCPE Actions Sanofi are exercised individually by the employees who hold units in the fund; fractional rights are exercised by the fund's supervisory board.

Voting rights attached to shares held by FCPE Sanofi Shares are also exercised individually by the employees who hold units in the fund; any rights not exercised by them are exercised by the fund's supervisory board.

In each case, the supervisory board includes an equal number of representatives of employees and of Sanofi management.

On April 30, 2019, our shareholders approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting options to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

- the authorization is valid for a period of 38 months, and any options granted may not give entitlement to a total number of shares exceeding 0.5% of the share capital as computed on the date of the decision of the Board of Directors to grant such options; see "— Stock Options" above.

On April 30, 2021, our shareholders also approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting existing or new restricted shares to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

- the authorization is valid for a period of 38 months, and is subject to a limit of 1.5% of the share capital as computed on the date of the decision of the Board of Directors to allot such shares; see "— Awards of Shares" above.

See also "Item 6. Directors, Senior Management and Employees — E. Share Ownership".

Decreases in share capital

In accordance with the provisions of the French Commercial Code, any decrease in our share capital requires approval by the shareholders entitled to vote at an extraordinary general meeting. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

In addition, specific rules exist to permit the cancellation of treasury shares, by which the shareholders' meeting may authorize the cancellation of up to a maximum of 10% of a company's share capital within any 24-month period. On April 30, 2021, our shareholders delegated to our Board of Directors for 26 months (i.e. until June 30, 2023) the right to reduce our share capital by cancelling our own shares.

Preemptive rights

According to the French Commercial Code, if we issue additional securities to be paid in cash, current shareholders will have preemptive rights to these securities on a pro rata basis. These preemptive rights require us to give priority treatment to current shareholders. The rights entitle the individual or entity that holds them to subscribe to the issuance of any securities that may increase the share capital of our Company by means of a cash payment or a set-off of cash debts. Preemptive rights are transferable during the subscription period relating to a particular offering. These rights may also be listed on Euronext Paris Stock Exchange.

Preemptive rights with respect to any particular offering may be waived by the affirmative vote of shareholders holding two-thirds of the shares entitled to vote at an extraordinary general meeting. Our Board of Directors and our independent auditors are required by French law to present reports that specifically address any proposal to waive preemptive rights. In the event of a waiver, the issuance of securities must be completed within the period prescribed by law. Shareholders may also notify us that they wish to waive their own preemptive rights with respect to any particular offering if they so choose.

The shareholders may decide at extraordinary general meetings to give the existing shareholders a non-transferable priority right to subscribe to the new securities, for a limited period of time.

In the event of a capital increase without preemptive rights to existing shareholders, French law requires that (i) the capital increase be made at a price determined by an extraordinary general meeting after submission of a report by the Board of Directors and (ii) the amount of a capital increase carried out each year in connection with an offering of the type specified in Article L. 411-2-1 of the French Monetary and Financial Code must be limited to 20% of a company's share capital.

Form, holding and transfer of shares

Form of shares

Our Articles of Association provide that the shares may be held in either bearer form or registered form at the option of the holder.

Holding of shares

In accordance with French law relating to the dematerialization of securities, shareholders' ownership rights are represented by book entries instead of share certificates. We maintain a share account with Euroclear France (a French clearing system, which holds securities for its participants) for all shares in registered form, which is administered by BNP Paribas Securities Services. In addition, we maintain separate accounts in the name of each shareholder either directly or, at a shareholder's request, through the shareholder's accredited intermediary. Each shareholder account shows the name of the holder and the number of shares held. BNP Paribas Securities Services

issues confirmations *(attestations d'inscription en compte)* to each registered shareholder as to shares registered in the shareholder's account, but these confirmations are not documents of title.

Shares of a listed company may also be issued in bearer form. Shares held in bearer form are held and registered on the shareholder's behalf in an account maintained by an accredited financial intermediary and are credited to an account at Euroclear France maintained by such intermediary. Each accredited financial intermediary maintains a record of shares held through it and provides the account holder with a securities account statement. Transfers of shares held in bearer form may only be made through accredited financial intermediaries and Euroclear France.

Shares held by persons who are not domiciled in France may be registered in the name of intermediaries who act on behalf of one or more investors. When shares are so held, we are entitled to request from such intermediaries the names of the investors. Also, we may request any legal entity *(personne morale)* which holds more than 2.5% of our shares or voting rights to disclose the name of any person who owns, directly or indirectly, more than one-third of its share capital or of its voting rights. A person not providing the complete requested information in time, or who provides incomplete or false information, will be deprived of its voting rights at shareholders' meetings and will have its payment of dividends withheld until it has provided the requested information in strict compliance with French law. If such person acted willfully, the person may be deprived by a French court of either its voting rights or its dividends or both for a period of up to five years.

Transfer of shares

Our Articles of Association do not contain any restrictions relating to the transfer of shares.

Registered shares must be converted into bearer form before being transferred on the Euronext Paris Stock Exchange on the shareholders' behalf and, accordingly, must be registered in an account maintained by an accredited financial intermediary on the shareholders' behalf. A shareholder may initiate a transfer by giving instructions to the relevant accredited financial intermediary.

A fee or commission is payable to the broker involved in the transaction, regardless of whether the transaction occurs within or outside France. Registration duty is currently payable in France if a written deed of sale and purchase (*acte*) is executed in France or outside France with respect to the shares of the Company.

Redemption of shares

Under French law, our Board of Directors is entitled to redeem a set number of shares as authorized by the extraordinary shareholders' meeting. In the case of such an authorization, the shares redeemed must be cancelled within one month after the end of the offer to purchase such shares from shareholders. However, shares redeemed on the open market do not need to be cancelled if the company redeeming the shares grants options on or awards those shares to its employees within one year following the acquisition. See also "— Trading in Our Own Shares" below.

Sinking fund provisions

Our Articles of Association do not provide for any sinking fund provisions.

Liability for further capital calls

Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable for further capital calls.

Liquidation rights

If we are liquidated, any assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will first be distributed to repay in full the par value of our shares. Any surplus will be distributed pro rata among shareholders in proportion to the par value of their shareholdings.

Requirements for holdings exceeding certain percentages

The French Commercial Code and AMF regulations provide that any individual or entity, acting alone or in concert with others, that becomes the owner, directly or indirectly, of more than 5%, 10%, 15%, 20%, 25%, 30%, $33^{1}/_{3}$%, 50%, $66^{2}/_{3}$%, 90% or 95% of the outstanding shares or voting rights of a listed company in France, such as our Company, or that increases or decreases its shareholding or voting rights above or below any of those percentages, must notify the company, before the end of the fourth trading day following the date it crosses the threshold, of the number of shares it holds and their voting rights. The individual or entity must also notify the AMF before the end of the fourth trading day following the date it crosses any such threshold. The AMF makes the notice public.

Pursuant to the French Commercial Code and the AMF General Regulation, the participation thresholds shall be calculated on the basis of the shares and voting rights owned, and shall take into account the shares and voting rights which are deemed to be shares and voting rights owned, even if the individual or entity does not itself hold shares or voting rights. In accordance with this deemed ownership principle, the individual or entity must take into account specific situations where shares and voting rights are deemed to be shares and voting rights owned when calculating the number of shares owned to be disclosed in the notifications to the Company and to the AMF. It includes among others situations where an individual or entity is entitled to acquire issued shares at its own initiative, immediately or at the end of a maturity period, under an agreement or a financial instrument, without set-off against the number of shares that this individual or entity is entitled to sell under another agreement or financial instrument. The individual or entity required to make such notification shall also take into account issued shares covered by an agreement or cash-settled financial instrument and having an economic effect for said individual or entity that is equivalent to owning such shares. In the cases of deemed ownership described above, the notification shall mention the type of deemed ownership and include a description of the main characteristics of the financial instrument or agreement with specific details required by the AMF General Regulation.

The AMF General Regulation provides that shares and voting rights subject to multiple cases of deemed ownership shall only be counted once.

When an individual or entity modifies the allocation between the shares it owns and its financial instruments or agreements deemed to be owned shares, it must disclose that change in a new notification. However, the change must only be disclosed if the acquisition of owned shares due to the settlement of the financial instruments or agreements causes the investor to cross a threshold.

Subject to certain limited exceptions, French law and AMF regulations impose additional reporting requirements on persons who acquire more than 10%, 15%, 20%, or 25% of the outstanding shares or voting rights of a company listed in France. These persons must file a report with the company and the AMF before the end of the fifth trading day following the date they cross any such threshold.

In the report, the acquirer will have to specify its intentions for the following six months including:

- whether it acts alone or in concert with others;
- the means of financing of the acquisition (the notifying party shall indicate in particular whether the acquisition is being financed with equity or debt, the main features of that debt, and, where applicable, the main guarantees given or received by the notifying party. The notifying party shall also indicate what portion of its holding, if any, it obtained through securities loans);
- whether or not it intends to continue its purchases;
- whether or not it intends to acquire control of the company in question;
- the strategy it contemplates *vis-à-vis* the issuer;
- the way it intends to implement its strategy, including: (i) any plans for a merger, reorganization, liquidation, or partial transfer of a substantial part of the assets of the issuer or of any other entity it controls within the meaning of Article L. 233-3 of the French Commercial Code, (ii) any plans to modify the business of the issuer, (iii) any plans to modify articles of association of the issuer, (iv) any plans to delist a category of the issuer's financial instruments, and (v) any plans to issue the issuer's financial instruments;
- any agreement for the temporary transfer of shares or voting rights of the issuer;
- the way it intends to settle its agreements or instruments on the shares or voting rights of the issuer mentioned in Article L. 233-9, 4° and 4° bis of the French Commercial Code; and
- whether it seeks representation on the Board of Directors.

The AMF makes the report public. Upon any change of intention within the six-month period following the filing of the report, it will have to file a new report for the following six-month period.

In order to enable shareholders to give the required notice, we must each month publish on our website and send the AMF a written notice setting forth the total number of our shares and voting rights (including treasury shares) whenever they vary from the figures previously published.

If any shareholder fails to comply with an applicable legal notification requirement, the shares in excess of the relevant threshold will be deprived of voting rights for all shareholders' meetings until the end of a two-year period following the date on which the owner complies with the notification requirements. In addition, any shareholder who fails to comply with these requirements may have all or part of its voting rights suspended for up to five years by the Commercial Court at the request of our Chairman, any shareholder or the AMF, and may be subject to criminal fines.

Under AMF regulations, and subject to limited exemptions granted by the AMF, any person or entity, acting alone or in concert, that crosses the threshold of 30% of the share capital or voting rights of a French listed company must initiate a public tender offer for the balance of the shares and securities giving access to the share capital or voting rights of such company. Cash-settled derivative instruments or agreements mentioned in Article L. 233-9, 4° bis of the French Commercial Code are not included in the calculation of the number of shares related to the mandatory public tender offer.

In addition, our Articles of Association provide that any person or entity, acting alone or in concert with others, who becomes the owner of 1%, or any multiple of 1% of our share capital or our voting rights, even beyond the minimum declaration limits permitted by the legal and regulatory provisions, must notify us by certified mail, return receipt requested, within five trading days, of the total number of shares and securities giving access to our share capital and voting rights that such person then owns. The same provisions of our Articles of Association apply whenever such owner increases or decreases its ownership of our share capital or our voting rights to such extent that it goes above or below one of the thresholds described in the preceding sentence. Any person or entity that fails to comply with such notification requirement will, upon the request of one or more shareholders holding at least 5% of our share capital or of our voting rights made at the general shareholders' meeting, be deprived of voting rights with respect to the shares in excess of the relevant threshold for all shareholders' meetings until the end of a two-year period following the date on which such person or entity complies with the notification requirements.

Change in control/Anti-takeover

There are no provisions in our Articles of Association that would have the effect of delaying, deferring or preventing a change in control of our Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving our Company or any of our subsidiaries. Further, there are no provisions in our Articles of Association that allow the issuance of preferred stock upon the occurrence of a takeover attempt or the addition of other "anti-takeover" measures without a shareholder vote.

Our Articles of Association do not include any provisions discriminating against any existing or prospective holder of our securities as a result of such shareholder owning a substantial number of shares.

See below additional information in relation to foreign direct investments under "— Ownership of Shares by Non-French Persons".

Trading in our own shares

Under French law, Sanofi may not issue shares to itself. However, we may, either directly or through a financial intermediary acting on our behalf, acquire up to 10% of our issued share capital within a maximum period of 18 months, provided our shares are listed on a regulated

market. Prior to acquiring our shares, we must publish a description of the share repurchase program *(descriptif du programme de rachat d'actions)*.

We may not cancel more than 10% of our issued share capital over any 24-month period. Our repurchase of shares must not result in our Company holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. We must hold any shares that we repurchase in registered form. These shares must be fully paid up. Shares repurchased by us continue to be deemed "issued" under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

The shareholders, at an extraordinary general shareholders meeting, may decide not to take these shares into account in determining the preemptive rights attached to the other shares. However, if the shareholders decide to take them into account, we must either sell the rights attached to the shares we hold on the market before the end of the subscription period or distribute them to the other shareholders on a pro rata basis.

On April 30, 2021, our shareholders approved a resolution authorizing us to repurchase up to 10% of our shares over an 18-month period. Under this authorization, the purchase price for each Sanofi ordinary share may not be greater than €150.00 and the maximum amount that Sanofi may pay for the repurchases is *€18,953,410,350*. This authorization was granted for a period of 18 months from April 30, 2021 and cancelled and replaced the authorization granted to the Board of Directors by the combined general meeting held on April 28, 2020. A description of this share repurchase program as adopted by the ordinary general meeting held on April 30, 2021 *(descriptif du programme de rachat d'actions)* was published on March 4, 2021.

Purposes of share repurchase programs

Under the European regulation 596/2014, dated April 16, 2014 on market abuse and its delegated regulation 2016/1052 on repurchase programs and stabilization measures, dated March 8, 2016 (which we refer to in this section as the "Regulation"), an issuer will benefit from a safe harbor for share transactions that comply with certain conditions relating in particular to the pricing, volume and timing of transactions (see below) and that are made in connection with a share repurchase program authorized by the shareholders the purpose of which is:

- to reduce the share capital through the cancellation of treasury shares;
- to meet obligations arising from debt financial instruments that are exchangeable into equity instruments; and/or
- to meet obligations arising from share option programs or other allocations of shares to employees or to members of the administrative, management or supervisory bodies of the issuer or of an associate company.

Safe harbor transactions will by definition not be considered market abuses under the Regulation. Transactions that are carried out for other purposes than those mentioned above do not qualify for the safe harbor.

However, as permitted by the Regulation, which provides for a presumption of legitimacy for existing market practices that do not constitute market manipulation and that conform with certain criteria, the AMF has established as a French accepted market practice, which therefore benefits from a presumption of legitimacy, the use of liquidity agreements for share purchases that are entered into with a financial services intermediary and that comply with the criteria set out by the AMF.

The AMF confirmed that all transactions directed at maintaining the liquidity of an issuer's shares must be conducted pursuant to a liquidity agreement with a financial services intermediary acting independently.

As of July 3, 2016, the purchase of shares that are subsequently used as acquisition currency in a business combination transaction, which the AMF previously permitted as an accepted market practice, is no longer considered as such, although such practice, while not benefiting from the presumption of legitimacy, is not prohibited under the Regulation.

Pricing, volume and other restrictions

In order to qualify for the safe harbor described above, the issuer must generally comply with the following pricing and volume restrictions:

- a share purchase must not be made at a price higher than the higher of the price of the last independent trade and the highest current independent bid on the trading venues where the purchase is carried out; and
- subject to certain exceptions for illiquid securities, the issuer must not purchase on any trading day more than 25% of the average daily volume of the shares on the regulated market on which the purchase is carried out. The average daily volume figure must be based on the average daily volume traded in the month preceding the month of public disclosure of the share repurchase program and fixed on that basis for the authorized period of that program. If the program does not make reference to this volume, the average daily volume figure must be based on the average daily volume traded in the 20 trading days preceding the date of purchase.

In addition, unless the issuer has in place a time-scheduled repurchase program or the repurchase program is lead-managed by an investment firm or a credit institution which makes its trading decisions concerning the timing of the purchase of the issuer's shares independently of the issuer, the issuer must not, for the duration of the repurchase program, engage in the following activities:

- selling its own shares;
- effecting any transaction during a closed period imposed by the applicable law of the Member State in which the transaction occurs (i.e. under French law, during the period between the date on which the company has knowledge of insider information and the date on which such information is made public, during the 30 calendar day period before the announcement of an interim financial report or a year-end report which the issuer is obliged to make public, and during the 15 calendar day period before the publication of the quarterly results); or
- effecting any transaction in securities with respect to which the issuer has decided to delay the public disclosure of inside information, in accordance with applicable rules.

Use of share repurchase programs

Pursuant to the AMF rules, issuers must immediately allocate the repurchased shares to one of the purposes provided for in the Regulation and must not subsequently use the shares for a different purpose. As an exception to the foregoing, shares repurchased with a view to covering stock option plans may, if no longer needed for this purpose, be re-allocated for cancellation or sold in compliance with AMF requirements relating in particular to blackout periods. Shares repurchased in connection with one of the market practices authorized by the AMF (see above) may also be re-allocated to one of the purposes contemplated by the Regulation or sold in compliance with AMF requirements. Shares repurchased with a view to their cancellation must be cancelled within 24 months following their acquisition.

During the year ended December 31, 2021, we used the authority delegated by our shareholders to repurchase our shares on the stock market.

Pursuant to our share repurchase programs authorized by our shareholders on April 28, 2020 and on April 30, 2021, we repurchased 4,523,957 of our shares for a weighted average price of €84.27, i.e. a total cost of €381 million. Brokerage fees, financial transaction taxes and the AMF contribution (net of income taxes) amounted to €0.89 million. Our Company did not resort to derivatives to repurchase our own shares.

During 2021, we did not carry out any cancellations of treasury shares.

During 2021, we did not use a liquidity contract.

During 2021, we did not allocate any shares to stock purchase option plans outstanding at December 31, 2021.

In 2021, in addition to the 8,280,347 shares allocated to performance share plans outstanding at December 31, 2020, Sanofi:

- purchased 1,758,569 of its shares at an average weighted price of €79.61 for a total amount of €139,999,948;
- transferred 1,786,343 of its shares to beneficiaries of performance shares at an average weighted price of €83.09 for a total amount of €148,430,715.

As of December 31, 2021, the 8,252,573 treasury shares held under our share repurchase program were allocated to covering performance share plans.

As of December 31, 2020, we had 838 shares created under the Action 2020 employee share ownership plan but not ultimately allocated to employees. They were sold in 2021.

In 2021, Sanofi purchased 2,765,388 shares at an average weighted price of €87.24 for a total amount of €241,246,756, which were allocated to a cancellation objective.

In addition, no shares were held to cover stock option plans or for liquidity purposes.

As of December 31, 2021, we directly owned 11,017,961 Sanofi shares with a par value of €2 representing around 0.87% of our share capital and with an estimated value of €927 million, based on the share price at the time of purchase.

Reporting obligations

Pursuant to the Regulation, the AMF Regulation and the French Commercial Code, issuers trading in their own shares are subject to the following reporting obligations:

- issuers must report all transactions in their own shares to the competent authority of each trading venue on which the shares are admitted to trading or are traded within seven trading days of the transaction in a prescribed format, unless such transactions are carried out pursuant to a liquidity agreement that complies with the ethical code approved by the AMF;
- issuers must declare to the AMF on a monthly basis all transactions completed under the share repurchase program unless they provide the same information on a weekly basis; and
- post on its website the transactions disclosed and keep that information available to the public for at least a 5-year period from the date of public disclosure.

Ownership of shares by non-French persons

The French Commercial Code and our Articles of Association currently do not limit the right of non-residents of France or non-French persons to own or, where applicable, to vote our securities. However, pursuant to the provisions of the French Monetary and Financial Code (CMF), any investment by any non-French citizen, any French citizen not residing in France, any non-French entity or any French entity controlled by such persons or entities that will result in the relevant investor (a) acquiring control of an entity registered in France, (b) acquiring all or part of a business line of an entity registered in France, or (c) for non-EU or non-EEA investors crossing, directly or indirectly, alone or in concert, a 25% threshold of voting rights in an entity registered in France, in each case, where all or part of the target's business and activity relate to a strategic sector, is subject to the prior authorization of the French Minister of the Economy. Under existing administrative rulings, ownership of $33^{1}/_{3}$% or more of our share capital or voting rights is regarded as a controlling interest, but a lower percentage might be held to be a controlling interest in certain circumstances depending upon factors such as:

- the acquiring party's intentions;
- the acquiring party's ability to elect directors; or
- financial reliance by the company on the acquiring party.

Such strategic sectors include (a) activities likely to prejudice national defense interests, participating in the exercise of official authority or likely to prejudice public order and public security (including activities related to weapons, dual-use goods and technologies, IT systems, cryptology, data capturing devices, gambling, toxic agents or data storage), (b) activities relating to essential infrastructure, goods or services (including energy, water, transportation, space, public health, telecommunications, farm products or media), (c) research and development activities related to critical technologies (including biotechnology, cybersecurity, artificial intelligence, robotics, additive

manufacturing, semiconductors, quantum technologies, energy storage and technologies related to generation of renewable energy) or dual-use goods and technologies.

This request for prior authorization must be filed with the French Ministry of Economy, which has 30 business days from receipt of the complete file to provide a first decision which may (i) unconditionally authorize the investment or (ii) indicate that further examination is required. In the latter case, the French Ministry of the Economy must make a second decision within 45 business days from its first decision. In the event of a lack of response from the French Ministry of the Economy within the above mentioned timeframe, the authorization will be deemed refused. If the authorization is granted, it may be subject to the signature of a letter of undertakings aimed at protecting French national interests. If an investment requiring the prior authorization of the French Minister of the Economy is completed without such authorization having been granted, the French Minister of the Economy might direct the relevant investor to (i) submit a request for authorization, (ii) have the previous situation restored at its own expense, or (iii) amend the investment. The relevant investor might also be found criminally liable and might be sanctioned with a fine which cannot exceed the greater of: (i) twice the amount of the relevant investment, (ii) 10% of the annual turnover before tax of the target company and (iii) €5 million (for a company) or €1 million (for an individual).

In the context of the ongoing COVID-19 pandemic, a decree dated July 22, 2020, as amended on December 28, 2020, added a new 10% threshold with respect to investments in and ownership of voting rights of companies organized under the laws of France whose shares are admitted to trading on a regulated market, in addition to the 25% threshold mentioned above. A “fast track” procedure is available for investors whose holdings exceed the 10% threshold but are less than the 25% threshold mentioned above. Pursuant to the decree dated December 22, 2021, such measures shall remain in force through December 31, 2022.

The CMF provides for statistical reporting requirements. Transactions by which non-French residents acquire at least 10% of the share capital or voting rights, or cross the 10% threshold, of a French resident company, are considered as foreign direct investments in France and are subject to statistical reporting requirements (Articles R. 152-1; R. 152-3 and R. 152-11 of the CMF). When the investment exceeds €125,500,000, companies must declare foreign transactions directly to the *Banque de France* within 20 business days following the date of certain direct foreign investments in us, including any purchase of ADSs. Failure to comply with such statistical reporting requirement may be sanctioned by five years’ imprisonment and a fine of a maximum amount equal to twice the amount which should have been reported, in accordance with Article L. 165-1 of the CMF. This amount may be increased fivefold if the violation is made by a legal entity.

Enforceability of civil liabilities

We are a limited liability company *(société anonyme)* organized under the laws of France, and most of our officers and directors reside outside the United States. In addition, a substantial portion of our assets is located outside of the United States.

As a result, it may be difficult for investors:

- to obtain jurisdiction over us or our non-US resident officers and directors in US courts, or obtain evidence in France or from French citizen or any individual being resident in France or any officer, representative, agent or employee of a legal person having its registered office or an establishment in a territory of France, in connection with those actions in actions predicated on the civil liability provisions of the US federal securities laws;
- to enforce in US courts judgments obtained in such actions against us or our non-US resident officers and directors;
- to bring an original action in a French court to enforce liabilities based upon the US federal securities laws against us or our non-US resident officers or directors; and
- to enforce in US courts against us or our directors in non-US courts, including French courts, judgments of US courts predicated upon the civil liability provisions of the US federal securities laws.

Nevertheless, a final judgment for the payment of money rendered by any federal or state court in the United States based on civil liability, whether or not predicated solely upon the US federal securities laws, would be recognized and enforced in France provided that a French judge considers that this judgment meets the French legal requirement concerning the recognition and the enforcement of foreign judgments and is capable of being immediately enforced in the United States. A French court is therefore likely to grant the enforcement of a foreign judgment without a review of the merits of the underlying claim, only if (1) that judgment was rendered by a court having jurisdiction over the matter as the dispute is clearly connected to the jurisdiction of such court, the choice of the US court was not fraudulent and the French courts did not have exclusive jurisdiction over the matter, (2) the judgment does not contravene international public policy rules, both pertaining to the merits and to the procedure of the case, including the defense rights, (3) the judgment is not tainted with fraud and (4) the judgment does not conflict with a French or foreign judgment (or an arbitral award) which has become effective in France.

In addition, French law guarantees full compensation for the harm suffered but is limited to the actual damages, so the victim does not suffer or benefit from the situation, it being specified that under French law, the principle of awarding punitive damages is not, per se, contrary to public order, provided the amount awarded is not disproportionate to the harm suffered and the defendant’s breach.

As a result, the enforcement, by US investors, of any judgments obtained in US courts in civil and commercial matters, including judgments under the US federal securities law against us or members of our Board of Directors, officers or certain experts named herein who are residents of France or countries other than the United States would be subject to the above conditions.

Finally, there may be doubt as to whether a French court would impose civil liability on us, the members of our Board of Directors, our officers or certain experts named herein in an original action predicated solely upon the US federal securities laws brought in a court of competent jurisdiction in France against us or such members, officers or experts, respectively.

C. Material Contracts

N/A

D. Exchange Controls

French exchange control regulations currently do not limit the amount of payments that we may remit to non-residents of France. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary.

E. Taxation

General

The following generally summarizes the material French and US federal income tax consequences to US holders (as defined below) of purchasing, owning and disposing of our ADSs and ordinary shares (collectively the "Securities"). This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our Securities. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

This summary does not constitute a legal opinion or tax advice. Holders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including the effect of any US federal, state, local or other national tax laws.

A set of tax rules is applicable to French assets that are held by or in foreign trusts. These rules provide inter alia for the inclusion of trust assets in the settlor's net assets for purpose of applying the French real estate wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the French real estate wealth tax and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to Securities held in trusts. *If Securities are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

The description of the French and US federal income tax consequences set forth below is based on the laws (including, for US federal income tax purposes, the Internal Revenue Code of 1986, as amended (the "Code"), final, temporary and proposed US Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof) in force as of the date of this annual report, the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994 (the "Treaty"), which entered into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax regulations issued by the French tax authorities within the *Bulletin Officiel des Finances Publiques-Impôts* (the "Regulations") in force as of the date of this report. *US holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits, especially with regard to the "Limitations on Benefits" provision, in light of their own particular circumstances.*

No advance ruling has been obtained with respect to the tax consequences of the acquisition, ownership or disposition of the Securities from either the French or US tax authorities. Thus, there can no assurances that either or both of such authorities will not take a position concerning said tax consequences different from that set out herein or that such a position would not be sustained by a court.

For the purposes of this discussion, a US holder is a beneficial owner of Securities that is (i) an individual who is a US citizen or resident for US federal income tax purposes, (ii) a US domestic corporation created or organized in or under the laws of the United States or any state thereof, including the District of Columbia, or (iii) certain estates or trusts that are subject to US tax jurisdiction. A non-US holder is a person other than a US holder.

If a partnership holds Securities, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. *If a US holder is an estate or trust or partner in a partnership that holds Securities, the holder is urged to consult its own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

This discussion is intended only as a general summary and does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the Securities to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. The discussion applies only to investors that hold our Securities as capital assets that have the US dollar as their functional currency, that are entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty, and whose ownership of the Securities is not effectively connected to a permanent establishment or a fixed base in France. Certain holders (including, but not limited to, US expatriates, partnerships or other entities classified as partnerships for US federal income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the Securities pursuant to the exercise of employee stock options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 5% or more of our voting stock or 5% or more of our outstanding share capital, dealers in securities or currencies, persons that elect to mark their securities to market for US federal income tax purposes, persons that acquire ADSs in "pre-release" transactions (i.e. prior to deposit of the relevant ordinary shares, although our depositary has indicated that such transactions have been halted) and persons holding Securities as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below. *Holders of Securities are advised to consult their own tax advisers with regard to the application of French tax law and US federal tax law to their particular situations, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction.*

French taxes

Estate and gift taxes and transfer taxes

In general, a transfer of Securities by gift or by reason of death of a US holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978, unless the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or the Securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Pursuant to Article 235 ter ZD of the French General Tax Code, purchases of Securities are subject to a 0.3% French tax on financial transactions (the "FTFF") provided that Sanofi's market capitalization exceeds €1 billion as of December 1 of the year preceding the taxation year. A list of companies whose market capitalization exceeds €1 billion as of December 1 of the year preceding the taxation year used to be published annually by the French Ministry of Economy. It is now published by the French tax authorities, and could be amended at any time. Pursuant to Regulations BOI-ANNX-000467-29/12/2021 issued on December 29, 2021, purchases of Sanofi's Securities in 2021 should be subject to the FTFF as the market capitalization of Sanofi exceeded 1 billion euros as of December 1, 2021. In accordance with Article 726-II-d of the French General Tax Code, purchases which are subject to the FTFF should however not be subject to transfer taxes *(droits d'enregistrement)* in France.

Wealth tax

The French wealth tax *(impôt de solidarité sur la fortune)* has been replaced with a French real estate wealth tax *(impôt sur la fortune immobilière)* with effect from January 1, 2018. French real estate wealth tax applies only to individuals and does not generally apply to the Securities if the holder is a US resident, as defined pursuant to the provisions of the Treaty, provided that the individual does not own directly or indirectly a shareholding exceeding 10% of the financial rights and voting rights.

US taxes

Ownership of the securities

Deposits and withdrawals by a US holder of ordinary shares in exchange for ADSs, will not be taxable events for US federal income tax purposes. For US tax purposes, holders of ADSs will be treated as owners of the ordinary shares represented by such ADSs. Accordingly, the discussion that follows regarding the US federal income tax consequences of acquiring, owning and disposing of ordinary shares is equally applicable to ADSs.

Information reporting and backup withholding tax

Distributions made to holders and proceeds paid from the sale, exchange, redemption or disposal of Securities may be subject to information reporting to the Internal Revenue Service. Such payments may be subject to backup withholding taxes unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not US persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non-US status in connection with payments received within the United States or through a US-related financial intermediary to establish that it is an exempt recipient. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's US federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

Foreign asset reporting

In addition, a US holder that is an individual (and, to the extent provided in future regulations, an entity), may be subject to recently-enacted reporting obligations with respect to ordinary shares and ADSs if the aggregate value of these and certain other "specified foreign financial assets" exceeds $50,000. If required, this disclosure is made by filing Form 8938 with the US Internal Revenue Service. Significant penalties can apply if holders are required to make this disclosure and fail to do so. In addition, a US holder should consider the possible obligation to file online a FinCEN Form 114 – Foreign Bank and Financial Accounts Report as a result of holding ordinary shares or ADSs. Holders are encouraged to consult their US tax advisors with respect to these and other reporting requirements that may apply to their acquisition of ordinary shares and ADSs.

State and local taxes

In addition to US federal income tax, US holders of Securities may be subject to US state and local taxes with respect to such Securities. *Holders of Securities are advised to consult their own tax advisers with regard to the application of US state and local income tax law to their particular situation.*

ADSs-Ordinary Shares

French taxes

Taxation of dividends

Under French law, dividends paid by a French corporation, such as Sanofi, to non-residents of France are generally subject to French withholding tax at a rate of 25% (12.8% for distributions made to individuals, and 15% for distributions made to not-for-profit organizations with a head office in a Member State of the European Economic Area which would be subject to the tax regime set forth under article 206 paragraph 2 of the French General Tax Code if its head office were located in France and which meet the criteria set forth in the Regulations BOI-RPPM-RCM-30-30-10-70-24/12/2019, No. 130). Dividends paid by a French corporation, such as Sanofi, towards non-cooperative States or territories, as defined in Article 238-0 A of the French General Tax Code, will generally be subject to French

withholding tax at a rate of 75%, irrespective of the tax residence of the beneficiary of the dividends if the dividends are received in such States or territories; however, eligible US holders entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty who are US residents, as defined pursuant to the provisions of the Treaty and who receive dividends in non-cooperative States or territories, will not be subject to this 75% withholding tax rate.

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible US holder who is a US resident as defined pursuant to the provisions of the Treaty and whose ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such US holder has in France, is reduced to 15%, or to 5% if such US holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuing company; such US holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any. For US holders that are not individuals but are US residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the "Limitation on Benefits" provision of the Treaty, are complicated, and certain technical changes were made to these requirements by the protocol of January 13, 2009. US holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible US holder may immediately be subject to the reduced rates of 5% or 15% provided that such holder establishes before the date of payment that it is a US resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000). Dividends paid to a US holder that has not filed the Form 5000 before the dividend payment date will be subject to French withholding tax at the rate of 25% and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other US holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

The depositary agrees to use reasonable efforts to follow the procedures established, or that may be established, by the French tax authorities (i) to enable eligible US holders to qualify for the reduced withholding tax rate provided by the Treaty, if available at the time the dividends are paid, or (ii) to recover any excess French withholding taxes initially withheld or deducted with respect to dividends and other distributions to which such US holders may be eligible from the French tax authorities and (iii) to recover any other available tax credits. In particular, associated forms (including Form 5000 and Form 5001, together with their instructions), will be made available by the depositary to all US holders registered with the depositary, and are also generally available from the US Internal Revenue Service.

The withholding tax refund, if any, ordinarily is paid within 12 months of filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend is paid.

Tax on sale or other disposition

In general, under the Treaty, a US holder who is a US resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption (other than redemption proceeds characterized as dividends under French domestic law), sale or exchange of ordinary shares or ADSs unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the US holder has in France. Special rules apply to holders who are residents of more than one country.

US Taxes

Taxation of dividends

For US federal income tax purposes, the gross amount of any distribution paid to US holders (that is, the net distribution received plus any tax withheld therefrom) will be treated as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of Sanofi (as determined under US federal income tax principles). Dividends paid by Sanofi will not be eligible for the dividends-received deduction generally allowed to corporate US holders.

Subject to certain exceptions for short-term and hedged positions, the US dollar amount of dividends received by an individual US holder with respect to the ADSs or our ordinary shares is currently subject to taxation at a maximum rate of 20% if the dividends are "qualified dividends". Dividends paid on the ordinary shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules and (ii) the issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company ("PFIC"). The Treaty has been approved for the purposes of the qualified dividend rules. Based on our financial statements and relevant market and shareholder data, we believe Sanofi was not a PFIC for US federal income tax purposes with respect to its 2020 taxable year. In addition, based on its current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, we do not anticipate that Sanofi will become a PFIC for its 2021 taxable year. *Holders of ordinary shares and ADSs should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.*

If you are a US holder, dividend income received by you with respect to ADSs or ordinary shares generally will be treated as foreign source income for foreign tax credit purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. Distributions out of earnings and profits with respect to the ADSs or ordinary shares generally will be treated as "passive category" income (or, in the case of certain US holders, "general category" income). Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the ADSs or ordinary shares may be claimed as a credit against the US federal income tax liability of a US holder if such US holder elects for that year to credit all foreign income taxes. Alternatively, such French withholding tax may be taken as a deduction against taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in Securities and may not be allowed in respect of certain arrangements in which a US holder's expected economic profit is insubstantial. *The US federal income tax rules governing the availability and computation of foreign tax credits are complex. US holders should consult their own tax advisers concerning the implications of these rules in light of their particular circumstances.*

To the extent that an amount received by a US holder exceeds the allocable share of our current and accumulated earnings and profits, such excess will be applied first to reduce such US holder's tax basis in its ordinary shares or ADSs and then, to the extent it exceeds the

US holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such ordinary shares or ADSs (see "— Tax on Sale or Other Disposition", below).

The amount of any distribution paid in euros will be equal to the US dollar value of the euro amount distributed, calculated by reference to the exchange rate in effect on the date the dividend is received by a US holder of ordinary shares (or by the depositary, in the case of ADSs) regardless of whether the payment is in fact converted into US dollars on such date. *US holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any euros received by a US holder that are converted into US dollars on a date subsequent to receipt.*

Distributions to holders of additional ordinary shares (or ADSs) with respect to their ordinary shares (or ADSs) that are made as part of a pro rata distribution to all ordinary shareholders generally will not be subject to US federal income tax. However, if a US holder has the option to receive a distribution in shares (or ADSs) or to receive cash in lieu of such shares (or ADSs), the distribution of shares (or ADSs) will be taxable as if the holder had received an amount equal to the fair market value of the distributed shares (or ADSs), and such holder's tax basis in the distributed shares (or ADSs) will be equal to such amount.

Tax on sale or other disposition

In general, for US federal income tax purposes, a US holder that sells, exchanges or otherwise disposes of its ordinary shares or ADSs will recognize capital gain or loss in an amount equal to the US dollar value of the difference between the amount realized for the ordinary shares or ADSs and the US holder's adjusted tax basis (determined in US dollars and under US federal income tax rules) in the ordinary shares or ADSs. Such gain or loss generally will be US-source gain or loss, and will be treated as long-term capital gain or loss if the US holder's holding period in the ordinary shares or ADSs exceeds one year at the time of disposition. If the US holder is an individual, any capital gain generally will be subject to US federal income tax at preferential rates (currently a maximum of 20%) if specified minimum holding periods are met. The deductibility of capital losses is subject to significant limitations.

Medicare tax

Certain US holders who are individuals, estates or trusts are required to pay a Medicare tax of 3.8% (in addition to taxes they would otherwise be subject to) on their "net investment income" which would include, among other things, dividends and capital gains from the ordinary shares and ADSs.

F. Dividends and Paying Agents

N/A

G. Statement by Experts

N/A

H. Documents on Display

We are subject to the information requirements of the US Securities Exchange Act of 1934, as amended, or Exchange Act, and, in accordance therewith, we are required to file reports, including this annual report on Form 20-F, and other information with the US Securities and Exchange Commission, or Commission, by electronic means.

You may review a copy of our filings with the Commission, as well as other information furnished to the Commission, including exhibits and schedules filed with it, at the Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information. In addition, the Commission maintains an Internet site at http://www.sec.gov that contains reports and other information regarding issuers that file electronically with the Commission (these documents are not incorporated by reference in this annual report).

I. Subsidiary Information

N/A

Item 11. Quantitative and Qualitative Disclosures about Market Risk[(1)]

General policy

Liquidity risk, foreign exchange risk and interest rate risk, as well as related counterparty risks, are managed centrally by our dedicated treasury team within the Group Finance Department. Where it is not possible to manage those risks centrally – in particular due to regulatory restrictions (such as foreign exchange controls) or local tax restrictions – credit facilities and/or currency lines, guaranteed whenever necessary by the parent company, are contracted by our subsidiaries locally with banks, under the supervision of the central treasury team.

Our financing and investment strategies, and our interest rate and currency hedging strategies, are reviewed monthly by the Group Finance Department.

Our policy prohibits the use of derivatives for speculative purposes.

Counterparty risk

Our financing and investing transactions, and our currency and interest rate hedges, are contracted with leading counterparties. We set limits for investment and derivative transactions with individual financial institutions, depending on the rating of each institution. Compliance with these limits, which are based on the notional amounts of the investments and the fair value of the hedging instruments, is monitored on a daily basis.

The table below shows our total exposure as of December 31, 2021 by rating and in terms of our percentage exposure to the dominant counterparty.

(€ million)	Cash and cash equivalents (excluding mutual funds) [(a)]	Notional amounts of currency hedges [(b)]	Fair value of currency hedges	Notional amounts of interest rate hedges [(b)]	Fair value of interest rate hedges	General corporate purpose credit facilities
AA	361	2,151	26	250	1	—
AA-	965	7,068	66	1,014	4	1,500
A+	853	7,341	84	1,102	3	4,000
A	1,282	4,593	39	1,125 [(c)]	(1)	1,500
A-	336	2,054	7	88	1	1,000
BBB+	88	—	—	—	—	—
Unallocated	156	—	—	—	—	—
Total	**4,041**	**23,207**	**222**	**3,579**	**7**	**8,000**
% / rating of dominant counterparty	17.0% / AA-	13.4% / AA-		13.3% / AA-		6% / A-

(a) Cash equivalents include mutual fund investments of €5,057 million.

(b) The notional amounts are translated into euros at the relevant closing exchange rate as of December 31, 2021.

(c) Includes interest rate swaps hedging fixed-rate bonds of €99 million held in a Professional Specialized Investment Fund dedicated to Sanofi, recognized in "Long-term loans, advances and other non-current receivables" (see Note D.7. to our consolidated financial statements).

As of December 31, 2021, we held investments in euro and US dollar denominated money-market mutual funds. Those instruments have low volatility, low sensitivity to interest rate risk, and a very low probability of loss of principal. The depositary banks of the mutual funds, and of Sanofi itself, have a long-term rating of at least A. Realization of counterparty risk could impact our liquidity in certain circumstances.

Foreign exchange risk

A. Operating foreign exchange risk

A substantial portion of our net sales is generated in countries where the euro, which is our reporting currency, is not the functional currency. In 2021, for example, 38.1% of our net sales were generated in the United States; 25.8% in Europe; and 36.1% in the Rest of the World region (see the definition in "Item 5. Operating and Financial Review and Prospects — A/ Operating results), including countries that are, or may in the future become, subject to exchange controls, of which 7.2% was generated in China and 4.4% in Japan. Although we also incur expenses in those countries, the impact of those expenses is not enough wholly to offset the impact of exchange rates on our net sales. Consequently, our operating income may be materially affected by fluctuations in exchange rates between the euro and other currencies. Sanofi operates a foreign exchange risk hedging policy to reduce the exposure of operating income to exchange rate movements. That policy involves regular assessments of Sanofi's worldwide foreign currency exposure, based on foreign currency transactions carried out by the parent company and its subsidiaries. Those transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of those transactions to exchange rate movements, Sanofi contracts hedges using liquid derivative instruments, mainly forward currency purchases and sales, and also foreign exchange swaps.

(1) The disclosures in this section supplement those provided in Note B.8.7. to the consolidated financial statements as regards the disclosure requirements of IFRS 7, and are covered by the independent registered public accounting firms' opinion on the consolidated financial statements.

The table below shows operating currency hedging instruments in place as of December 31, 2021, with the notional amount translated into euros at the relevant closing exchange rate (see Note D.20. to the consolidated financial statements for the accounting classification of those instruments as of December 31, 2021).

Operating foreign exchange derivatives as of December 31, 2021

(€ million)	Notional amount	Fair value
Forward currency sales	**3,912**	**4**
of which US dollar	1,392	5
of which Chinese yuan renminbi	665	(2)
of which Singapore dollar	355	(1)
of which Japanese yen	199	3
of which Mexican peso	122	(1)
Forward currency purchases	**2,374**	**6**
of which US dollar	833	(2)
of which Singapore dollar	696	7
of which Chinese yuan renminbi	255	—
of which Russian rouble	77	—
of which Japanese yen	72	(1)
Total	**6,286**	**10**

The above positions mainly hedge future material foreign-currency cash flows arising after the end of the reporting period in relation to transactions carried out during the year ended December 31, 2021 and recognized in the balance sheet at that date. Gains and losses on hedging instruments (forward contracts) are calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Due to this hedging relationship, the commercial foreign exchange profit or loss on these items (hedging instruments and hedged transactions) will be immaterial in 2022.

B. Financial foreign exchange risk

The cash pooling arrangements for foreign subsidiaries outside the euro zone, and some of Sanofi's financing activities, expose certain Sanofi entities to financial foreign exchange risk (i.e. the risk of changes in the value of borrowings and loans denominated in a currency other than the functional currency of the borrower or lender). That foreign exchange exposure is hedged using derivative instruments (foreign exchange swaps, forward contracts or currency swaps) that alter the currency split of Sanofi's net debt once those instruments are taken into account.

The table below shows financial currency hedging instruments in place as of December 31, 2021, with the notional amounts translated into euros at the relevant closing exchange rate (see also Note D.20. to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2021).

Financial foreign exchange derivatives as of December 31, 2021

(€ million)	Notional amount		Fair value	Expiry
Forward currency sales	**7,655**		**15**	
of which US dollar	*5,384*	(a)	*23*	*2022*
of which Hungarian forint	*756*	(b)	*4*	*2022*
of which Brazilian real	*95*	(c)	*(3)*	*2022*
Forward currency purchases	**9,293**		**197**	
of which US dollar	*4,816*	(d) (e)	*128*	*2022*
of which Singapore dollar	*2,910*	(f)	*75*	*2022*
of which Hungarian forint	*865*		*(5)*	*2022*
Total	**16,948**		**212**	

(a) Includes forward sales with a notional amount of $3,615 million expiring in 2022, designated as a hedge of Sanofi's net investment in Bioverativ. As of December 31, 2021, the fair value of these forward contracts represented an asset of €20 million; the opposite entry was recognized in "Other comprehensive income", with the impact on financial income and expense being immaterial.

(b) Includes forward sales with a notional amount of HUF 279 billion expiring in 2022, designated as a hedge of Sanofi's net investment in Chinoin. As of December 31, 2021, the fair value of these forward contracts represented an asset of €2 million; the opposite entry was recognized in "Other comprehensive income", with the impact on financial income and expense being immaterial.

(c) Includes forward sales with a notional amount of BRL 600 million expiring in 2022, designated as a hedge of Sanofi's net investment in Medley Farmaceutica. As of December 31, 2021, the fair value of these forward contracts represented a liability of €3 million; the opposite entry was recognized in "Other comprehensive income", with the impact on financial income and expense being immaterial.

(d) Includes forward purchases with a notional amount of $550 million expiring in 2022, designated as a fair value hedge of the exposure of $550 million of bond issues to fluctuations in the EUR/USD spot rate. As of December 31, 2021, the fair value of the contracts was an asset of €19 million, the opposite entry for €0.1 million of which was credited to "Other comprehensive income" under under cost of hedging accounting treatment.

(e) Includes currency swaps with a notional amount of $1,000 million receive 0.22% pay EUR -0.63% expiring in 2022, designated as a cash flow hedge of $1,000 million of bond issues. As of December 31, 2021, the fair value of the swaps was an asset of €23 million.

(f) Includes forward purchases with a notional amount of SGD1,000 million expiring in 2022, designated as a fair value hedge of the exposure of an equivalent amount of intragroup current accounts to fluctuations in the EUR/SGD spot rate. As of December 31, 2021, the fair value of the contracts was an asset of €20 million, the opposite entry for €1.5 million of which was debited to "Other comprehensive income" under cost of hedging accounting treatment.

These hedging instruments generate a net financial gain or loss arising from the interest rate differential between the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency borrowing and loans is offset by the change in the intrinsic value of the hedging instruments. The interest rate differential is recognized within cost of net debt (see Note D.29. to our consolidated financial statements). We may also hedge some future foreign-currency investment or divestment cash flows.

C. Other foreign exchange risks

A significant proportion of our net assets is denominated in US dollars (see Note D.35. to the consolidated financial statements). As a result, any fluctuation in the exchange rate of the US dollar against the euro automatically impacts the amount of our equity as expressed in euros.

In addition, we use the euro as our reporting currency. Consequently, if one or more European Union Member States were to abandon the euro as a currency, the resulting economic upheavals – in particular, fluctuations in exchange rates – could have a significant impact on the terms under which we can obtain financing and on our financial results, the extent and consequences of which are not currently foreseeable.

Liquidity risk

We operate a centralized treasury platform whereby all surplus cash and financing needs of our subsidiaries are invested with or funded by the parent company (where permitted by local legislation). The central treasury department manages our current and projected financing, and ensures that Sanofi is able to meet its financial commitments by maintaining sufficient cash and confirmed credit facilities for the size of our operations and the maturity of our debt (see Notes D.17.1.c and D.17.1.g to the consolidated financial statements).

We diversify our short-term investments with leading counterparties using money-market products with instant access or with a maturity of less than three months.

As of December 31, 2021, cash and cash equivalents amounted to €10,098 million, and short-term investments predominantly comprised:

- collective investments in euro and US dollar denominated money-market mutual funds. All such funds can be traded on a daily basis and the amount invested in each fund may not exceed 10% of the aggregate amount invested in such funds;
- amounts invested directly with banks and non-financial institutions in the form of instant access deposits, term deposits, and Negotiable European Commercial Paper with a maturity of no more than three months.

In addition, to optimize the liquidity/return profile of our short-term investments, we had €198 million invested in term deposits as of December 31, 2021, expiring in December 2021 and presented within "Other current financial assets" (see Note D.11.).

As of December 31, 2021 we also had €8 billion of undrawn general corporate purpose confirmed credit facilities, half of which expires in December 2022 and half in December 2026. Those credit facilities are not subject to financial covenant ratios.

Our policy is to diversify our sources of funding through public or private issuances of debt securities, in the United States (shelf registration statement) and Europe (Euro Medium Term Note program). In addition, our A-1+/P-1 short-term rating gives us access to commercial paper programs in the United States, and to Negotiable European Commercial Paper programs in France. The average maturity of our total debt was 5.05 years as of December 31, 2021, compared with 5.5 years as of December 31, 2020. During 2021, we did not draw down on our Negotiable European Commercial Paper programs in France. Average drawdowns under the US commercial paper program during 2021 were €2.0 billion (with a maximum of €3.6 billion); the average maturity of those drawdowns was two months. As of December 31, 2021, neither of those programs was being utilized.

In the event of a liquidity crisis, we could be exposed to difficulties in calling up our available cash, a scarcity of sources of funding including the above-mentioned programs, and/or a deterioration in their terms. This situation could damage our capacity to refinance our debt or to issue new debt on reasonable terms.

Interest rate risk

Sanofi issues debt in two currencies, the euro and the US dollar, and also invests its cash and cash equivalents in those currencies. Sanofi also operates cash pooling arrangements to manage the surplus cash and short-term liquidity needs of foreign subsidiaries located outside the euro zone.

To optimize the cost of debt or reduce the volatility of debt and manage its exposure to financial foreign exchange risk, Sanofi uses derivative instruments (interest rate swaps, currency swaps, foreign exchange swaps and forward contracts) that alter the fixed/floating rate split and the currency split of its net debt.

The projected full-year sensitivity to interest rate fluctuations of our debt, net of cash and cash equivalents for 2022 is as follows:

Change in short-term interest rates	Impact on pre-tax net income (€ million)	Impact on pre-tax income/(expense) recognized directly in equity (€ million)
+100 bp	74	–
+25 bp	19	–
-25 bp	(19)	–
-100 bp	(74)	–

Stock market risk

It is our policy not to trade on the stock market for speculative purposes.

During 2019, Sanofi contracted derivative instruments (collars) on 593,712 shares of Dexcom Inc; the collars were designated as fair value hedges of the Dexcom shares. As of December 31, 2021 they had a negative fair value of €16 million, recognized in full in ***Other comprehensive income***.

Item 12. Description of Securities other than Equity Securities

12.A. Debt securities

Not applicable.

12.B. Warrants and rights

Not applicable.

12.C. Other securities

Not applicable.

12.D. American depositary shares

General

JPMorgan Chase Bank, N.A. ("JPMorgan"), as depositary, issues Sanofi ADSs in certificated form (evidenced by an ADR) or book-entry form. Each ADR is a certificate evidencing a specific number of Sanofi ADSs. Each Sanofi ADS represents one-half of one Sanofi ordinary share (or the right to receive one-half of one Sanofi ordinary share) deposited with the Paris, France office of BNP Paribas, as custodian. Each Sanofi ADS also represents an interest in any other securities, cash or other property that may be held by the depositary under the deposit agreement. The depositary's office is located at 383 Madison Avenue, 11th Floor, New York, New York 10179.

A holder may hold Sanofi ADSs either directly or indirectly through his or her broker or other financial institution. The following description assumes holders hold their Sanofi ADSs directly, in certificated form evidenced by ADRs. Holders who hold the Sanofi ADSs indirectly must rely on the procedures of their broker or other financial institution to assert the rights of ADR holders described in this section. Holders should consult with their broker or financial institution to find out what those procedures are.

Holders of Sanofi ADSs do not have the same rights as holders of Sanofi shares. French law governs shareholder rights. The rights of holders of Sanofi ADSs are set forth in the deposit agreement between Sanofi and JPMorgan and in the ADR. New York law governs the deposit agreement and the ADRs.

The following is a summary of certain terms of the deposit agreement, as amended. Our form of second amended and restated deposit agreement was filed with the SEC as an exhibit to our Post-Effective Amendment No. 1 to Form F-6 filed on February 13, 2015. The form of Amendment No. 1 to our form of second amended and restated deposit agreement was filed as an exhibit to our Post-Effective Amendment No. 2 to Form F-6 filed with the SEC on August 4, 2020. To the extent any portion of the amendment and restatement would prejudice any substantial existing right of holders of ADSs under the first amended and restated deposit agreement, such portion shall not become effective as to such holders until 30 days after holders have received notice thereof. For more complete information, holders should read the entire second amended and restated deposit agreement, Amendment No. 1 and the ADR itself. Holders may also inspect a copy of the current deposit agreement and Amendment No. 1 at the depositary's office.

Share dividends and other distributions

Receipt of dividends and other distributions

The depositary has agreed to pay to holders of Sanofi ADSs the cash dividends or other distributions that it or the custodian receives on the deposited Sanofi ordinary shares and other deposited securities after deducting its fees, charges and expenses and taxes withheld. Holders of Sanofi ADSs will receive these distributions in proportion to the number of Sanofi ADSs that they hold.

Cash. The depositary will convert any cash dividend or other cash distribution paid on the shares into US dollars if, in its judgment, it can do so on a reasonable basis and can transfer the US dollars to the United States. If the depositary determines that such a conversion and transfer is not possible, or if any approval from the French government is needed and cannot be obtained within a reasonable period, then the depositary may (1) distribute the foreign currency received by it to the holders of Sanofi ADSs or (2) hold the foreign currency distribution (uninvested and without liability for any interest) for the account of holders of Sanofi ADSs.

In addition, if any conversion of foreign currency, in whole or in part, cannot be effected to some holders of Sanofi ADSs, the deposit agreement allows the depositary to distribute the dividends only to those ADR holders to whom it is possible to do so. It will hold the foreign currency it cannot convert into US dollars for the account of the ADR holders who have not been paid. It will not invest the funds it holds and it will not be liable for any interest.

Before making a distribution, any withholding taxes that must be paid under French law will be deducted. The depositary will distribute only whole US dollars and cents and will round fractional cents down to the nearest whole cent. ***Exchange rate fluctuations during a period when the depositary cannot convert euros into US dollars may result in holders losing some or all of the value of a distribution.***

Shares. The depositary may, and at our request will, distribute new ADRs representing any shares we distribute as a dividend or free distribution, if we furnish it promptly with satisfactory evidence that it is legal to do so. At its option, the depositary may distribute fractional Sanofi ADSs. If the depositary does not distribute additional Sanofi ADSs, the outstanding ADRs will also represent the new shares. The

depositary may withhold any tax or other governmental charges, or require the payment of any required fees and expenses, prior to making any distribution of additional Sanofi ADSs.

Rights to Receive Additional Shares. If we offer holders of Sanofi ordinary shares any rights to subscribe for additional shares or any other rights, the depositary, after consultation with us, will, in its discretion, either (1) make these rights available to holders or (2) dispose of such rights on behalf of holders and make the net proceeds available to holders. The depositary may make rights available to certain holders but not others if it determines it is lawful and feasible to do so. However, if, under the terms of the offering or for any other reason, the depositary may not make such rights available or dispose of such rights and make the net proceeds available, it will allow the rights to lapse. In that case, holders of Sanofi ADSs will receive no value for them.

In circumstances where rights would not otherwise be distributed by the depositary to holders of Sanofi ADSs, a holder of Sanofi ADSs may nonetheless request, and will receive from the depositary, any instruments or other documents necessary to exercise the rights allocable to that holder if the depositary first receives written notice from Sanofi that (1) Sanofi has elected, in its sole discretion, to permit the rights to be exercised and (2) such holder has executed the documents Sanofi has determined, in its sole discretion, are reasonably required under applicable law.

If the depositary makes rights available to holders of Sanofi ADSs, upon instruction from such holders, it will exercise the rights and purchase the shares on such holder's behalf. The depositary will then deposit the shares and deliver ADRs to such holders. It will only exercise rights if holders of Sanofi ADSs pay it the exercise price and any other charges the rights require such holders to pay.

US securities laws may restrict the sale, deposit, cancellation or transfer of ADRs issued upon exercise of rights. For example, holders of Sanofi ADSs may not be able to trade such Sanofi ADSs freely in the United States. In this case, the depositary may deliver Sanofi ADSs under a separate restricted deposit agreement that will contain the same provisions as the deposit agreement, except for changes needed to implement the required restrictions.

Other Distributions. The depositary will distribute to holders of Sanofi ADSs anything else we may distribute on deposited securities (after deduction or upon payment of fees and expenses or any taxes or other governmental charges) by any means it thinks is legal, equitable and practical. If, for any reason, it cannot make the distribution in that way, the depositary may sell what we distributed and distribute the net proceeds of the sale in the same way it distributes cash dividends, or it may choose any other method to distribute the property it deems equitable and practicable.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of Sanofi ADSs. We have no obligation to register Sanofi ADSs, shares, rights or other securities under the US Securities Act of 1933, as amended. We also have no obligation to take any other action to permit the distribution of ADRs, shares, rights or anything else to holders of Sanofi ADSs. This means that holders may not receive the distribution we make on our shares or any value for them if it is illegal or impractical for the depositary to make them available to such holders.

Elective Distributions. Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to holders of Sanofi ADSs. In that case, we will assist the depositary in determining whether that distribution is lawful and reasonably practicable. The depositary will make the election available to holders of Sanofi ADSs only if it is reasonably practicable and if we have provided all the documentation contemplated in the deposit agreement. In that case, the depositary will establish procedures to enable holders of Sanofi ADSs to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement. If the election is not made available to holders of Sanofi ADSs, such holders will receive either cash or additional Sanofi ADSs, depending on what a shareholder in France would receive for failing to make an election, as more fully described in the deposit agreement.

Deposit, withdrawal and cancellation

Delivery of ADRs

The depositary will deliver ADRs if the holder or his or her broker deposit shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of Sanofi ADSs in the names the holder requests and will deliver the ADRs to the persons the holder requests at its office.

Obtaining Sanofi ordinary shares

A holder may turn in his or her ADRs at the depositary's office. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver (1) the underlying shares to an account designated by the holder and (2) any other deposited securities underlying the ADR at the office of a custodian or, at the holder's request, risk and expense, the depositary will deliver the deposited securities at its office.

Voting rights

A holder may instruct the depositary to vote the Sanofi ordinary shares underlying his or her Sanofi ADSs at any meeting of Sanofi shareholders, but only if we request that the depositary ask for holder instructions. Otherwise, holders will not be able to exercise their right to vote unless they withdraw the underlying ordinary shares from the ADR program and vote as an ordinary shareholder. However, holders may not know about the meeting sufficiently in advance to timely withdraw the underlying ordinary shares.

If we ask for holder instructions in connection with a meeting of Sanofi shareholders, the depositary will provide materials to holders of Sanofi ADSs in the manner described under the heading "Notices and Reports; Rights of Holders to Inspect Books" below. For any instructions to be valid, the depositary must receive them on or before the date specified in the materials distributed by the depositary. The depositary will endeavor, in so far as practical, subject to French law and the provisions of our *statuts*, to vote or to have its agents vote the shares or other deposited securities as holders may validly instruct. The depositary will only vote or attempt to vote shares as holders validly instruct.

We cannot guarantee holders that they will receive the voting materials with sufficient time to enable them to return any voting instructions to the depositary in a timely manner to vote their shares. As long as they act in good faith, neither the depositary nor its agents will be responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. ***This means that holders may not be able to exercise their right to vote and there may be nothing holders can do if the shares represented by their ADSs are not voted as they requested.***

Similar to our shares, Sanofi ADSs evidenced by ADRs that are registered in the name of the same owner for at least two (2) years are eligible for double voting rights so long as certain procedures are followed, as set out in the deposit agreement. For additional information regarding double voting rights, see "Item 10. Additional Information — B. Memorandum and Articles of Association — Voting Rights".

The deposit agreement allows the depositary and Sanofi to change the voting procedures or require additional voting procedures in addition to the ones described above if necessary or appropriate. ***For example, holders might be required to arrange to have their Sanofi ADSs deposited in a blocked account for a specified period of time prior to a shareholders' meeting in order to be allowed to give voting instructions.***

Notices and reports; rights of holders to inspect books

On or before the first date on which we give notice, by publication or otherwise, of any meeting of holders of shares or other deposited securities, or of any adjourned meeting of such holders, or of the taking of any action in respect of any cash or other distributions or the offering of any rights, we will transmit to the depositary a copy of the notice.

Upon notice of any meeting of holders of shares or other deposited securities, if requested in writing by Sanofi, the depositary will, as soon as practicable, mail to the holders of Sanofi ADSs a notice, the form of which is in the discretion of the depositary, containing (1) a summary in English of the information contained in the notice of meeting provided by Sanofi to the depositary, (2) a statement that the holders as of the close of business on a specified record date will be entitled, subject to any applicable provision of French law and of our *statuts*, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the amount of shares or other deposited securities represented by their respective ADSs and (3) a statement as to the manner in which such instructions may be given. Notwithstanding the above, the depositary may, to the extent not prohibited by law or regulations, or by the requirements of NASDAQ, in lieu of distribution of the materials provided to the depositary as described above, distribute to the holders a notice that provides holders with, or otherwise publicizes to holders, instructions on how to retrieve such materials or receive such materials upon request (i.e., by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

The depositary will make available for inspection by ADS holders at the depositary's office any reports and communications, including any proxy soliciting material, received from us that are both (1) received by the depositary as the holder of the deposited securities and (2) made generally available to the holders of such deposited securities by us. The depositary will also, upon written request, send to ADS holders copies of such reports when furnished by us pursuant to the deposit agreement. Any such reports and communications, including any such proxy soliciting material, furnished to the depositary by us will be furnished in English to the extent such materials are required to be translated into English pursuant to any regulations of the SEC.

The depositary will keep books for the registration of ADRs and transfers of ADRs that at all reasonable times will be open for inspection by the holders provided that such inspection is not for the purpose of communicating with holders in the interest of a business or object other than our business or a matter related to the deposit agreement or the ADRs.

Fees and expenses

Fees payable by ADS holders

Pursuant to the deposit agreement, holders of our ADSs may have to pay to JPMorgan, either directly or indirectly, fees or charges up to the amounts set forth in the table below.

Associated Fee	Depositary Action
$5.00 or less per 100 ADSs (or portion thereof)	Execution and delivery of ADRs for distributions and dividends in shares and rights to subscribe for additional shares or rights of any other nature and surrender of ADRs for the purposes of withdrawal, including the termination of the deposit agreement.
$0.05 or less per ADS (or portion thereof)	Any cash distribution made pursuant to the deposit agreement, including, among other things: • cash distributions or dividends; • distributions other than cash, shares or rights; • distributions in shares; and • rights of any other nature, including rights to subscribe for additional shares.
$0.05 or less per ADS per calendar year (or portion thereof)	Services performed in administering the ADRs (which fee may be charged on a periodic basis during each calendar year)
Registration fees in effect for the registration of transfers of shares generally on the share register of the company or foreign registrar and applicable to transfers of shares to or from the name of JPMorgan or its nominee to the custodian or its nominee on the making of deposits and withdrawals	As applicable
A fee equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities	Distributions of securities other than cash, shares or rights
A fee for the reimbursement of such fees, charges and expenses as are incurred by JPMorgan, its agents (and their agents), including BNP Paribas, as custodian (by deductions from cash dividends or other cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them)	Compliance with foreign exchange control regulations or any law or regulation relating to foreign investment, servicing of shares or other deposited securities, sale of securities, delivery of deposited securities or otherwise
Expenses incurred by JPMorgan	• Cable, telex and facsimile transmission (where expressly provided for in the deposit agreement) • Foreign currency conversion into US dollars

In addition to the fees outlined above, each holder will be responsible for any taxes or other governmental charges payable on his or her Sanofi ADSs or on the deposited securities underlying his or her Sanofi ADSs. The depositary may refuse to transfer a holder's Sanofi ADSs or allow a holder to withdraw the deposited securities underlying his or her Sanofi ADSs until such taxes or other charges are paid. It may apply payments owed to a holder or sell deposited securities underlying a holder's Sanofi ADSs to pay any taxes owed, and the holder will remain liable for any deficiency. If it sells deposited securities, it will, if appropriate, reduce the number of Sanofi ADSs to reflect the sale and pay to the holder any proceeds, or send to the holder any property, remaining after it has paid the taxes. For additional information regarding taxation, see "Item 10. Additional Information — E. Taxation".

Fees paid to Sanofi by the depositary

JPMorgan, as depositary, has agreed to reimburse Sanofi for certain expenses (subject to certain limits) Sanofi incurs relating to legal fees, investor relations servicing, investor-related presentations, ADR-related advertising and public relations in those jurisdictions in which the ADRs may be listed or otherwise quoted, investor relations channel, perception studies, accountants' fees in relation to our annual report on Form 20-F or any other expenses directly or indirectly relating to managing the program or servicing the ADR holders. The depositary has also agreed to provide additional amounts to us based on certain performance indicators relating to the ADR facility and fees collected by it. From January 1, 2021 to December 31, 2021, we received a total amount of $18,297,473.45 from JPMorgan. In addition to these payments, JPMorgan has agreed to waive servicing fees we may incur in connection with routine corporate actions such as annual general meetings and dividend distributions, as well as for other assistance JPMorgan may provide to us, such as preparation of tax and regulatory compliance documents for holders and investor relations advisory services.

Changes affecting deposited securities

If we:

- change the nominal or par value of our Sanofi ordinary shares;
- recapitalize, reorganize, merge or consolidate, liquidate, sell assets, or take any similar action;
- reclassify, split up or consolidate any of the deposited securities; or
- distribute securities on the deposited securities that are not distributed to holders;

then either:

- the cash, shares or other securities received by the depositary will become deposited securities and each Sanofi ADS will automatically represent its equal share of the new deposited securities; or
- the depositary may, and will if we ask it to, distribute some or all of the cash, shares or other securities it receives. It may also deliver new ADRs or ask holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

Disclosure of interests

The obligation of a holder or other person with an interest in our shares to disclose information under French law and under our *statuts* also applies to holders and any other persons, other than the depositary, who have an interest in the Sanofi ADSs. The consequences for failing to comply with these provisions are the same for holders and any other persons with an interest as a holder of our ordinary shares. For additional information regarding these obligations, see "Item 10. Additional Information — B. Memorandum and Articles of Association — Requirements for Holdings Exceeding Certain Percentages".

Amendment and termination

We may agree with the depositary to amend the deposit agreement and the ADRs without the consent of the ADS holders for any reason. If the amendment adds or increases fees or charges, except for taxes and other governmental charges or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses, or prejudices a substantial right of holders of Sanofi ADSs, it will only become effective 30 days after the depositary notifies such holders of the amendment. However, we may not be able to provide holders of Sanofi ADSs with prior notice of the effectiveness of any modifications or supplements that are required to accommodate compliance with applicable provisions of law, whether or not those modifications or supplements could be considered to be materially prejudicial to the substantial rights of holders of Sanofi ADSs. ***At the time an amendment becomes effective, such holders will be considered, by continuing to hold their ADR, to have agreed to the amendment and to be bound by the ADR and the deposit agreement as amended.***

The depositary will terminate the agreement if we ask it to do so. The depositary may also terminate the agreement if the depositary has told us that it would like to resign and we have not appointed a new depositary bank within 90 days. In both cases, the depositary must notify holders of Sanofi ADSs at least 30 days before termination.

After termination, the depositary and its agents will be required to do only the following under the deposit agreement: (1) collect distributions on the deposited securities, (2) sell rights and other property as provided in the deposit agreement and (3) deliver shares and other deposited securities upon cancellation of ADRs. Six months or more after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it receives on the sale, as well as any other cash it is holding under the deposit agreement, for the pro rata benefit of the holders of Sanofi ADSs that have not surrendered their Sanofi ADSs. It will have no liability for interest. Upon termination of the deposit agreement, the depositary's only obligations will be to account for the proceeds of the sale and other cash and with respect to indemnification. After termination, our only obligation will be with respect to indemnification and to pay certain amounts to the depositary.

Limitations on obligations and liability to holders of Sanofi ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary, and it limits our liability and the liability of the depositary. In particular, please note the following:

- we and the depositary are obligated only to take the actions specifically set forth in the deposit agreement without gross negligence or bad faith;
- we and the depositary are not liable if either is prevented or delayed by law or circumstances beyond its control from performing its obligations under the deposit agreement;
- we and the depositary are not liable if either exercises, or fails to exercise, any discretion permitted under the deposit agreement;
- we and the depositary have no obligation to become involved in a lawsuit or other proceeding related to the Sanofi ADSs or the deposit agreement on holders' behalf or on behalf of any other party, unless indemnity satisfactory to it against all expense and liability is furnished as often as may be required;
- we and the depositary are not liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system or the custodian, subject to certain exceptions and to the extent the custodian is not a branch or affiliate of JPMorgan;
- the depositary is not liable for the price received in connection with any sale of securities, the timing thereof or any delays, acts, omissions to act, errors, defaults or negligence on the part of the party so retained in connection with any such sale or proposed sale;
- we and the depositary may rely without any liability upon any written notice, request, direction, instruction or other document believed by either of us to be genuine and to have been signed or presented by the proper parties; and
- we and the depositary are not liable for any action or nonaction taken in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, any ADS holder, or any other person believed in good faith to be competent to give such advice or information.

In addition, the depositary will not be liable for any acts or omissions made by a successor depositary. Moreover, neither we nor the depositary nor any of our respective agents will be liable to any holder of Sanofi ADSs for any indirect, special, punitive or consequential damages.

Pursuant to the terms of the deposit agreement, we and the depositary have agreed to indemnify each other under certain circumstances.

Requirements for depositary actions

Before the depositary will deliver or register the transfer of Sanofi ADSs, make a distribution on Sanofi ADSs or process a withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver Sanofi ADSs, register transfers of Sanofi ADSs or permit withdrawals of shares when the transfer books of the depositary or our transfer books are closed, or at any time if the depositary or we think it advisable to do so.

Right to receive the shares underlying the Sanofi ADSs

Holders have the right to cancel their Sanofi ADSs and withdraw the underlying Sanofi ordinary shares at any time except:

- when temporary delays arise when we or the depositary have closed our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends;
- when the holder or other holders of Sanofi ADSs seeking to withdraw shares owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to Sanofi ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-release of Sanofi ADSs

The provisions of our form of second amended and restated deposit agreement, as amended, do not permit the pre-release of the Sanofi ADSs.

Part II

Item 13. Defaults, Dividend Arrearages and Delinquencies

N/A

Item 14. Material Modifications to the Rights of Security Holders

N/A

Item 15. Controls and Procedures

(a) Our Chief Executive Officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective to ensure that material information relating to Sanofi was timely made known to them by others within Sanofi.

(b) Report of Management on Internal Control Over Financial Reporting.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2021 based on the framework in "Internal Control — Integrated Framework" (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2021 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers Audit (PCAOB ID 1347) and Ernst & Young et Autres (PCAOB ID 1704) independent registered public accounting firms, as stated in their report on the Company's internal control over financial reporting as of December 31, 2021, which is included herein. See paragraph (c) of the present Item 15., below.

(c) See report of PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, included under "Item 18. Financial Statements" on page F-3.

(d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

The Audit Committee is composed of Fabienne Lecorvaisier, Christophe Babule and Diane Souza. Gilles Schnepp was also a member of the Committee until December 15, 2021.

Our Board of Directors has determined that all directors are independent financial experts within the meaning of Section 407 of the Sarbanes-Oxley Act of 2002.

The Board of Directors deemed Fabienne Lecorvaisier to be a financial expert based on her education and experience in corporate finance in various international banks and as Chief Financial Officer of Essilor and Air Liquide. She is now Executive Vice President, in charge of Sustainable Development, Public and International Affairs as well as the supervision of the Social Programs and the General Secretariat of Air Liquide Group.

The Board of Directors deemed Christophe Babule to be a financial expert based on his education and experience in audit and corporate finance in major corporations and as Executive Vice President and Chief Financial Officer of L'Oréal. He has also served as director of L'Oréal USA Inc.

The Board of Directors deemed Diane Souza to be a financial expert based on her education (she is a certified public accountant) and experience in audit and tax in major international corporations, as Chief Financial Officer of Aetna's Guaranteed Products business, and as Chief Executive Officer of the UnitedHealthcare Specialty Benefits.

The Board of Directors deemed Gilles Schnepp, member of the Committee until December 15, 2021, to be a financial expert based on his education and experience in audit and corporate finance in major corporations and as a member of the board of directors of Saint-Gobain and Danone. He also served as Chairman and Chief Executive Officer of Legrand and Vice President of the supervisory board of PSA (now Stellantis).

The Board of Directors has determined that all three directors meet the independence criteria of US Securities and Exchange Commission Rule 10A-3, although only Fabienne Lecorvaisier and Diane Souza meet the French AFEP-MEDEF Code criteria of independence applied by the Board of Directors for general corporate governance purposes (see Item 16G, below).

Item 16B. Code of Ethics

We have adopted a financial code of ethics, as defined in Item 16B. of Form 20-F under the Exchange Act. Our financial code of ethics applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions, as designated from time to time. Our financial code of ethics is available on our website at www.sanofi.com (information on our website is not incorporated by reference in this annual report). A copy of our financial code of ethics may also be obtained free of charge by addressing a written request to the attention of Individual Shareholder Relations at our headquarters in Paris. We will disclose any amendment to the provisions of such financial code of ethics on our website.

Item 16C. Principal Accountants' Fees and Services

See Note E. to our consolidated financial statements included at Item 18 of this annual report.

Item 16D. Exemptions from the Listing Standards for Audit Committees

N/A

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In 2021, Sanofi made the following purchases of its ordinary shares.

Period	(A) Total Number of Shares Purchased	(B) Average Price Paid per Share	(C) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs[(a)]	(D) Approximate Value of Shares that May Yet Be Purchased Under the Plans or Programs[(b)]
January 2021	1,758,569	79.61	1,758,569	18,208
December 2021	2,765,388	87.24	2,765,388	18,643

(a) The Company was authorized to repurchase up to €18,807,691,650 of shares for a period of eighteen months (i.e., through October 28, 2021) by the Annual Shareholders' Meeting held on April 28, 2020. Then, the Company was authorized to repurchase up to €18,884,575,950 of shares for a period of eighteen months (i.e., through October 30, 2022) by the Annual Shareholders' Meeting held on April 30, 2021.

(b) Millions of euros.

For more information see "Item 10.B. Memorandum and Articles of Association — Use of Share Repurchase Programs".

Item 16F. Change in Registrant's Certifying Accountant

N/A

Item 16G. Corporate Governance

Sanofi is incorporated under the laws of France, with securities listed on regulated public markets in the United States (NASDAQ Global Select Market) and France (Euronext Paris). Consequently, as described further in our annual report, our corporate governance framework reflects the mandatory provisions of French corporate law, the securities laws and regulations of France and the United States and the rules of the aforementioned public markets.

As a "foreign private issuer," as defined in rules promulgated under the US Securities Exchange Act of 1934, as amended, (the "Exchange Act"), Sanofi is permitted, pursuant to NASDAQ Stock Market Rule 5615(a)(3), to follow its home country practice in lieu of certain NASDAQ corporate governance requirements applicable to US corporations listed on the NASDAQ Stock Market. Sanofi has informed NASDAQ that it intends to follow corporate governance standards under French law to the extent permitted by the NASDAQ Stock Market rules and US securities laws, as further discussed below.

We generally follow the "AFEP-MEDEF" corporate governance recommendations for French listed issuers (hereafter referred to as the "AFEP-MEDEF Code"). As a result, our corporate governance framework is similar in many respects to, and provides investor protections that are comparable to – or in some cases, more stringent than – the corresponding rules of the NASDAQ Global Select Market. Nevertheless, there are important differences to keep in mind.

In line with NASDAQ Stock Market rules applicable to domestic issuers, a majority of Sanofi's Board of Directors is comprised of independent directors. Sanofi evaluates the independence of members of our Board of Directors using the standards of the French AFEP-MEDEF Code as the principal reference. We believe that AFEP-MEDEF's overarching criteria for independence – no relationship of any kind whatsoever with the Company, its group or the management of either that is such as to color a Board member's judgment – are on the whole consistent with the goals of the NASDAQ Global Select Market's rules although the specific tests proposed under the two standards may vary on some points. We have complied with the Audit Committee independence and other requirements of the Rule 10A-3 under the Exchange Act, adopted pursuant to the Sarbanes-Oxley Act of 2002. Our Audit Committee includes one member, Christophe Babule, who is considered non-independent under the AFEP-MEDEF Code, and which is permitted under the AFEP-MEDEF Code, although this would not be permitted under the rules of the NASDAQ Global Select Market for domestic issuers. Each member of our Compensation Committee meets the independence standards of the AFEP-MEDEF Code and the independence requirements of NASDAQ's listing rules and Rule 10A-3 promulgated under the Sarbanes-Oxley Act of 2002, as amended.

Sanofi follows the recommendation of the AFEP-MEDEF Code that at least one meeting not attended by the company's executive officers be organized each year. Accordingly, Sanofi's Board Charter provides that the Board of Directors shall organize at least two meetings a year without its executive officers, thereby providing the Chairman with the option to include or not directors representing employees or any other Group employee, as the case may require, depending on the agenda of the meeting. Sanofi's practice in that respect departs from NASDAQ's Listing Rule 5605(b)(2), which provides that independent directors must have regularly scheduled meetings at which only independent directors are present.

Under French law, the committees of our Board of Directors are advisory only, and where the NASDAQ Rule 5600 Series would vest certain decision-making powers with specific committees by delegation (e.g. the appointment of Sanofi's auditors by the Audit Committee), under French law, our Board of Directors remains the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the shareholders of Sanofi voting at the Shareholders' General Meeting that have the authority to appoint our auditors upon consideration of the proposal of our Board of Directors, although our Board Charter provides that the Board of Directors will make its proposal on the basis of the recommendation of our Audit Committee. We believe that this requirement of French law, together with the additional legal requirement that two sets of statutory

auditors be appointed, is in line with the NASDAQ Global Select Market's underlying goal of ensuring that the audit of our accounts be conducted by auditors independent from company management.

In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option or restricted share plans or other share capital increases, whether for the benefit of senior management or employees, may only be adopted by the Board of Directors pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the Board the authority to implement such operations.

As described above, a number of issues, which could be resolved directly by a board or its committees in the United States, require the additional protection of direct shareholder consultation in France.

Because we are a "foreign private issuer" as described above, our Chief Executive Officer and our Chief Financial Officer issue the certifications required by §Section 302 and §Section 906 of the Sarbanes-Oxley Act of 2002 on an annual basis (with the filing of our annual report on Form 20-F) rather than on a quarterly basis as would be the case of a US corporation filing quarterly reports on Form 10- Q.

French corporate law provides that the Board of Directors must vote to approve a broadly defined range of transactions that could potentially create conflicts of interest between Sanofi on the one hand and its directors and Chief Executive Officer on the other hand, which are then presented to shareholders for approval at the next annual meeting. This legal safeguard operates in place of certain provisions of the NASDAQ Stock Market Listing Rules.

Sanofi is governed by the French Commercial Code, which provides that an ordinary general meeting of the shareholders may validly deliberate when first convened if the shareholders present or represented hold at least one-fifth of the voting shares. If it is reconvened, no quorum is required. The French Commercial Code further provides that the shareholders at an extraordinary general meeting may validly deliberate when first convened only if the shareholders present or represented hold at least one-quarter of the voting shares and, if reconvened, one-fifth of the voting shares. Therefore, Sanofi will not follow NASDAQ's Rule 5620(c), which provides that the minimum quorum requirement for a meeting of shareholders is $33\frac{1}{3}\%$ of the outstanding common voting shares of the company. In accordance with the provisions of the French Commercial Code, the required majority for the adoption of a decision is a simple majority (for an ordinary general meeting of the shareholders) or a two-thirds majority (for an extraordinary general meeting) of the votes cast by the shareholders present or represented.

Item 16H. Mine Safety Disclosure

N/A

Item 16I. Disclosure regarding foreign jurisdictions that prevent inspections

N/A

Part III

Item 17. Financial Statements

See Item 18.

Item 18. Financial Statements

See pages F-1 through F-100 incorporated herein by reference.

Item 19. Exhibits

1.1.	Articles of association (statuts) of Sanofi (English translation).
1.2.	Board Charter (Règlement Intérieur) of Sanofi (English translation).
2.	The total amount of long-term debt securities authorized under any instrument does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. We hereby agree to furnish to the SEC, upon its request, a copy of any instrument defining the rights of holders of long-term debt of the Company or of its subsidiaries for which consolidated or unconsolidated financial statements are required to be filed.
8.1.	List of significant subsidiaries, see “Item 4. Information on the Company — C. Organizational Structure” of this 20-F.
12.1.	Certification by Paul Hudson, Chief Executive Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002.
12.2.	Certification by Jean-Baptiste Chasseloup de Chatillon, Principal Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002.
13.1.	Certification by Paul Hudson, Chief Executive Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002.
13.2.	Certification by Jean-Baptiste Chasseloup de Chatillon, Principal Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002.
23.1.	Consent of Ernst & Young et Autres dated February 23, 2022.
23.2.	Consent of PricewaterhouseCoopers Audit dated February 23, 2022.

Signatures

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Sanofi	
By:	/s/ PAUL HUDSON
Name:	**Paul Hudson**
Title:	**Chief Executive Officer**

Date: February 23, 2022.

Report of Independent Registered Public Accounting Firms

To the Shareholders and the Board of Directors of Sanofi,

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Sanofi and its subsidiaries (together the "Company") as of December 31, 2021, 2020, and 2019, the related consolidated income statements, statements of comprehensive income, statements of changes in equity and statements of cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, 2020, and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board and in conformity with International Financial Reporting Standards as endorsed by the European Union.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 23, 2022 expressed an unqualified opinion thereon.

Change in Accounting Principle

As discussed in Notes A.2.1 and D.19.1 to the consolidated financial statements, the Company changed the manner in which it accounts for costs of configuring or customizing a supplier's application software in a Software as a Service (SaaS) arrangement (IAS 38, Intangibles Assets) and for the attribution of benefits to periods of service for certain defined benefit plans (IAS 19, Employee Benefits) in the years ended December 31, 2021, 2020 and 2019 due to the first time application of related IFRIC IC decisions from March 2021 and April 2021, respectively.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are public accounting firms registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Recoverable amount of other intangible assets

Description of the Matter	Other intangible assets amounted to €21,407 million at December 31, 2021. Management recognized impairment losses of €192 million for the year ended December 31, 2021. As described in Notes B.6.1., D.4. and D.5. to the consolidated financial statements, other intangible assets not yet available for use are tested for impairment annually and whenever events or circumstances indicate that impairment might exist. Other intangible assets that generate separate cash flows and assets included in cash-generating units (CGUs) are assessed for impairment when events or changes in circumstances indicate that the asset or CGU may be impaired. Management estimates the recoverable amount of the asset and recognizes an impairment loss if the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of the asset is the higher of its fair value less costs to sell or its value in use. Value in use is determined by management using estimated future cash flows generated by the asset or CGU which are discounted and prepared using the same methods as those used in the initial measurement of the assets and on the basis of medium-term strategic plans. Management cash flow projections include significant assumptions related to mid and long-term sales forecasts; perpetual growth or attrition rate, where applicable; discount rate; and probability of success of current research and development projects. The principal considerations for our determination that auditing the recoverable amount of other intangible assets is especially challenging, subjective, and required complex auditor judgment related to the significant judgments made by management when developing the significant assumptions utilized in the future cash flow projections as described above. In addition, the audit effort involved professionals with specialized skills and knowledge to assist in performing the audit procedures and evaluating the audit evidence obtained.
How We Addressed the Matter in Our Audit	Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to management's other intangible assets impairment assessment, including controls over the significant assumptions used in the impairment testing of the other intangible assets. These audit procedures also included, among others, evaluating the appropriateness of the discounted cash flow model; testing the completeness, accuracy, and relevance of underlying data used in the model; and evaluating the significant assumptions used by management as described above. Evaluating management's assumptions involved evaluating whether the assumptions used by management were reasonable by considering the current and past performance of other intangible assets in comparison to management's previous forecasts and current trends, the consistency of certain assumptions with external market and industry data, and whether these assumptions were consistent with evidence obtained in other areas of the audit such as internal company communications and presentations and external communications. We involved our professionals with specialized skills and knowledge to assist us in the assessment of the discount rate used by management.

Valuation of the provisions for rebates relating to Sanofi's business in the United States – Medicaid, Medicare and Managed Care

Description of the Matter	As described in Notes B.13.1. and D.23. to the consolidated financial statements, products sold in the United States are covered by various Government and State programs (of which Medicaid and Medicare are the most significant) and are subject to commercial agreements with healthcare authorities and certain customers and distributors. Estimates of discounts and rebates incentives (hereinafter the "Rebates") to be provided to customers under those arrangements are recognized as a reduction of gross sales in the period in which the underlying sales are recognized. Provisions for the Medicaid, Medicare and Managed Care Rebates amounted to €1,244 million, €941 million and €896 million, respectively, at December 31, 2021. The Rebates estimated by management are based on the nature and patient profile of the underlying product; the applicable regulations or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers; historical data relating to similar contracts; past experience and sales growth trends for the same or similar products; actual inventory levels in distribution channels, monitored by Sanofi using internal sales data and externally provided data; market trends including competition, pricing and demand. The principal considerations for our determination that auditing the provisions for Rebates relating to the Company's business in the United States is especially challenging and required complex auditor judgment related to the significant judgment by management due to significant measurement uncertainty involved in developing these provisions. These provisions are estimated based on multiple factors as described above.
How We Addressed the Matter in Our Audit	Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to management's estimates of the provisions for Rebates relating to the Company's business in the United States, including controls over the assumptions used to estimate these Rebates. These procedures also included, among others, developing an independent estimate of the provisions for Rebates by utilizing third party data on inventory levels in distribution channels, volume, changes to price, the terms of the specific rebate programs, and the historical trend of actual rebate claims paid. The independent estimate was compared to the provisions recorded by the Company. Additionally, these procedures included testing actual rebate claims paid and evaluating the contractual terms of the Company's rebate agreements.

Provisions for product liability risks, litigation and other and contingent liabilities

Description of the Matter	Provisions for product liability risks, litigation and other were recorded in an amount of €1,374 million at December 31, 2021. As described in Notes B.12., D.19.3. and D.22. to the consolidated financial statements, the Company records such provisions when an outflow of resources is probable and the amount of the outflow can be reliably estimated. The Company also discloses the contingent liabilities in circumstances where management is unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding, or a cash outflow is not probable. The pharmaceutical industry is highly regulated, which increases the inherent risk of litigation and arbitration. The Company is involved in litigation, arbitration and other legal proceedings. These proceedings are typically related to litigation concerning product liability claims, intellectual property rights, competition law and trade practices, as well as claims under warranties or indemnification arrangements relating to business divestments. The issues raised by these claims are highly complex and subject to substantial uncertainties; therefore, the probability of loss and an estimation of damages are difficult to ascertain. The principal considerations for our determination that auditing the provision for product liability risks, litigation and other, and auditing the contingent liabilities is especially challenging, subjective and required complex auditor judgment resulted from the determination that the measurement of the provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions by management. There is inherent uncertainty related to these cases and in estimating the likelihood and outcome of the cases.
How We Addressed the Matter in Our Audit	Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to management's evaluation of the provisions for product liability risks, litigation and other, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as the need for and the level of financial statement disclosures. These procedures also included, among others, obtaining and evaluating the letters of audit inquiry with internal and external legal counsels, evaluating management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable through the evaluation of the legal letters and summaries of the proceedings and lawsuit correspondence. We also evaluated the Company's disclosures for contingent liabilities.

Uncertain tax positions

Description of the Matter	As described in Notes B.22. and D.19.4. to the consolidated financial statements, the Company has recorded liabilities pertaining to uncertain tax positions of €1,463 million at December 31, 2021. The Company operates in multiple tax jurisdictions, carrying out potentially complex transactions that require management to make judgments and estimates as to the tax impact of those transactions. The positions adopted by the Company in tax matters are based on its interpretation of tax laws and regulations. Some of those positions may be subject to uncertainty. In such cases, the Company assesses the amount of the tax liability on the basis of the following assumptions: that its position will be examined by one or more tax authorities on the basis of all relevant information; that a technical assessment is carried out with reference to legislation, case law, regulations, and established practice; and that each position is assessed individually (or collectively where appropriate), with no offset or aggregation between positions. Those assumptions are assessed on the basis of facts and circumstances existing at the end of the reporting period. When an uncertain tax liability is regarded as probable, it is measured on the basis of the Company's best estimate. The principal considerations for our determination that auditing uncertain tax positions is especially challenging, subjective and required complex auditor judgment related to the significant judgment by management when determining the liability for uncertain tax positions, including a high degree of estimation uncertainty of certain assumptions and interpretations of the tax laws and regulations underlying the positions. In addition, we involved tax professionals to assist in performing these procedures and evaluating the audit evidence obtained.
How We Addressed the Matter in Our Audit	Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to the identification and recognition of the liability for uncertain tax positions, management's assessment and interpretation of tax laws and its evaluation of which tax positions may not be sustained upon audit and controls over measurement of the liability. These procedures also included, among others, testing the completeness and accuracy of the underlying data used in the calculation of the liability for uncertain tax positions and evaluating the assumptions used by management when determining its tax positions, the status of tax audits and investigations, and the potential impact of past claims. Our tax professionals assisted in evaluating the reasonableness of management's assessments by comparing the positions taken by management with tax regulations and past decisions from tax authorities and where applicable, evaluating opinions from the Company's external tax advisors. We also evaluated the disclosures provided in the notes to the consolidated financial statements concerning uncertain tax positions.

/s/ PricewaterhouseCoopers Audit

/s/ Dominique Ménard /s/ Cédric Mazille

/s/ Ernst & Young et Autres

Ernst & Young et Autres and PricewaterhouseCoopers Audit have served as the Company's auditors since 1986 and 1999, respectively.

Neuilly-sur-Seine and Paris-La Défense, February 23, 2022

Report of Independent Registered Public Accounting Firms

To the Shareholders and the Board of Directors of Sanofi,

Opinion on Internal Control over Financial Reporting

We have audited Sanofi and its subsidiaries' (together the "Company") internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2021, 2020 and 2019, the related consolidated income statements, statements of comprehensive income, statements of changes in equity and statements of cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). Our report dated February 23, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are public accounting firms registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers Audit

/s/ Dominique Ménard

/s/ Cédric Mazille

/s/ Ernst & Young et Autres

Neuilly-sur-Seine and Paris-La Défense, February 23, 2022

2021 Consolidated financial statements

The financial statements are presented in accordance with International Financial Reporting Standards (IFRS).

Consolidated balance sheets - assets

(€ million)	Note	December 31, 2021	December 31, 2020 [(a)]	December 31, 2019 [(a)]
Property, plant and equipment	D.3.1.	10,028	9,365	9,717
Right-of-use assets	D.3.2.	1,948	1,198	1,300
Goodwill	D.4.	48,056	44,364	44,519
Other intangible assets	D.4.	21,407	18,341	16,509
Investments accounted for using the equity method	D.6.	250	201	3,591
Other non-current assets	D.7.	3,127	2,734	2,503
Non-current income tax assets		175	248	164
Deferred tax assets	D.14.	4,598	4,176	5,391
Non-current assets		**89,589**	**80,627**	**83,694**
Inventories	D.9.	8,715	8,352	7,994
Accounts receivable	D.10.	7,568	7,491	7,937
Other current assets	D.11.	3,571	2,737	2,445
Current income tax assets		612	1,208	808
Cash and cash equivalents	D.13. - D.17.1.	10,098	13,915	9,427
Current assets		**30,564**	**33,703**	**28,611**
Assets held for sale or exchange	D.8.	89	83	325
Total assets		**120,242**	**114,413**	**112,630**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

Consolidated balance sheets – equity and liabilities

(€ million)	Note	December 31, 2021	December 31, 2020 [a]	December 31, 2019 [a]
Equity attributable to equity holders of Sanofi	D.15.	68,681	63,106	59,056
Equity attributable to non-controlling interests	D.16.	350	146	174
Total equity		**69,031**	**63,252**	**59,230**
Long-term debt	D.17.1.	17,123	19,745	20,131
Non-current lease liabilities	D.17.2.	1,839	931	987
Non-current liabilities related to business combinations and to non-controlling interests	D.18.	577	387	508
Non-current provisions and other non-current liabilities	D.19.	6,721	7,315	7,413
Non-current income tax liabilities	D.19.4.	2,039	1,733	1,680
Deferred tax liabilities	D.14.	1,617	1,770	2,294
Non-current liabilities		**29,916**	**31,881**	**33,013**
Accounts payable		6,180	5,295	5,313
Current liabilities related to business combinations and to non-controlling interests	D.18.	137	218	292
Current provisions and other current liabilities	D.19.5.	11,217	10,132	9,703
Current income tax liabilities		309	604	258
Current lease liabilities	D.17.2.	269	232	261
Short-term debt and current portion of long-term debt	D.17.1.	3,183	2,767	4,554
Current liabilities		**21,295**	**19,248**	**20,381**
Liabilities related to assets held for sale or exchange	D.8.	—	32	6
Total equity and liabilities		**120,242**	**114,413**	**112,630**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

Consolidated income statements

(€ million)	Note	2021	2020 [a]	2019 [a]
Net sales	**D.35.1.**	**37,761**	**36,041**	**36,126**
Other revenues		1,414	1,328	1,505
Cost of sales		(12,255)	(12,159)	(11,979)
Gross profit		**26,920**	**25,210**	**25,652**
Research and development expenses		(5,692)	(5,530)	(6,020)
Selling and general expenses		(9,555)	(9,391)	(9,884)
Other operating income	D.25.	859	697	783
Other operating expenses	D.26.	(1,805)	(1,415)	(1,207)
Amortization of intangible assets	D.4.	(1,580)	(1,681)	(2,146)
Impairment of intangible assets	D.5.	(192)	(330)	(3,604)
Fair value remeasurement of contingent consideration	D.12. - D.18.	(4)	124	238
Restructuring costs and similar items	D.27.	(820)	(1,089)	(1,088)
Other gains and losses, and litigation	D.28.	(5)	136	327
Gain on Regeneron investment arising from transaction of May 29, 2020	D.2.	—	7,382	—
Operating income		**8,126**	**14,113**	**3,051**
Financial expenses	D.29.	(368)	(388)	(440)
Financial income	D.29.	40	53	141
Income before tax and investments accounted for using the equity method	**D.35.1.**	**7,798**	**13,778**	**2,752**
Income tax expense	D.30.	(1,558)	(1,807)	(121)
Share of profit/(loss) from investments accounted for using the equity method	D.31.	39	359	255
Net income excluding the exchanged/held-for-exchange Animal Health business		**6,279**	**12,330**	**2,886**
Net income/(loss) of the exchanged/held-for-exchange Animal Health business[b]		—	—	(101)
Net income		**6,279**	**12,330**	**2,785**
Net income attributable to non-controlling interests	D.32.	56	36	31
Net income attributable to equity holders of Sanofi		**6,223**	**12,294**	**2,754**
Average number of shares outstanding (million)	D.15.9.	1,252.5	1,253.6	1,249.9
Average number of shares after dilution (million)	D.15.9.	1,257.9	1,260.1	1,257.1
• Basic earnings per share (in euros)		4.97	9.81	2.20
• Basic earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)		4.97	9.81	2.28
• Diluted earnings per share (in euros)		4.95	9.76	2.19
• Diluted earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)		4.95	9.76	2.27

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

(b) Net income/losses arising from the divestment of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations).

Consolidated statements of comprehensive income

(€ million)		2021	2020 [(a)]	2019 [(a)]
Net income		**6,279**	**12,330**	**2,785**
Attributable to equity holders of Sanofi		*6,223*	*12,294*	*2,754*
Attributable to non-controlling interests		*56*	*36*	*31*
Other comprehensive income:				
• Actuarial gains/(losses)	D.15.7.	686	(267)	(336)
• Change in fair value of equity instruments included in financial assets and financial liabilities	D.15.7.	165	320	106
• Tax effects	D.15.7.	(54)	(39)	101
Sub-total: items not subsequently reclassifiable to profit or loss (A)		**797**	**14**	**(129)**
• Change in fair value of debt instruments included in financial assets	D.15.7.	(21)	15	28
• Change in fair value of cash flow hedges	D.15.7.	(6)	4	(13)
• Change in currency translation differences	D.15.7.	2,459	(3,976)	751
• Tax effects	D.15.7.	78	(64)	47
Sub-total: items subsequently reclassifiable to profit or loss (B)		**2,510**	**(4,021)**	**813**
Other comprehensive income for the period, net of taxes (A+B)		**3,307**	**(4,007)**	**684**
Comprehensive income		**9,586**	**8,323**	**3,469**
Attributable to equity holders of Sanofi		*9,519*	*8,307*	*3,439*
Attributable to non-controlling interests		*67*	*16*	*30*

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

Consolidated statements of changes in equity

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi [a]	Attributable to non-controlling interests	Total equity
Balance at January 1, 2019	**2,495**	**13**	**(153)**	**53,093**	**3,596**	**(168)**	**58,876**	**159**	**59,035**
Impact of applying IFRIC agenda decision on IAS 19[a]	—	—	—	171	—	—	171	—	171
Impact of applying IFRIC agenda decision on SaaS arrangements[a]				(31)			(31)		(31)
Balance at January 1, 2019 after impact of IFRIC agenda decisions on IAS 19 and SaaS arrangements(a)	**2,495**	**13**	**(153)**	**53,233**	**3,596**	**(168)**	**59,016**	**159**	**59,175**
Other comprehensive income for the period[a]	—	—	—	(128)	—	813	685	(1)	684
Net income for the period[a]	—	—	—	2,754	—	—	2,754	31	2,785
Comprehensive income for the period[a]	**—**	**—**	**—**	**2,626**	**—**	**813**	**3,439**	**30**	**3,469**
Dividend paid out of 2018 earnings (€3.07 per share)	—	—	—	(3,834)	—	—	(3,834)	—	(3,834)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(14)	(14)
Share repurchase program[b]	—	—	(12)	—	—	—	(12)	—	(12)
Share-based payment plans:									
• Exercise of stock options[b]	6	141	—	—	—	—	147	—	147
• Issuance of restricted shares and vesting of existing restricted shares[b][d]	7	(7)	153	(153)	—	—	—	—	—
• Proceeds from sale of treasury shares on exercise of stock options	—	—	3	—	—	—	3	—	3
• Value of services obtained from employees	—	—	—	—	252	—	252	—	252
• Tax effects of the exercise of stock options	—	—	—	—	15	—	15	—	15
Other changes arising from issuance of restricted shares[c]	—	—	—	30	—	—	30	—	30
Change in non-controlling interests without loss of control	—	—	—	(7)	—	—	(7)	(1)	(8)
Other[e]	—	—	—	7	—	—	7	—	7
Balance at December 31, 2019	**2,508**	**147**	**(9)**	**51,902**	**3,863**	**645**	**59,056**	**174**	**59,230**

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
Balance at January 1, 2020[a]	**2,508**	**147**	**(9)**	**51,902**	**3,863**	**645**	**59,056**	**174**	**59,230**
Other comprehensive income for the period[a]	—	—	—	14	—	(4,001)	(3,987)	(20)	(4,007)
Net income for the period[a]	—	—	—	12,294	—	—	12,294	36	12,330
Comprehensive income for the period[a]	**—**	**—**	**—**	**12,308**	**—**	**(4,001)**	**8,307**	**16**	**8,323**
Dividend paid out of 2019 earnings (€3.15 per share)	—	—	—	(3,937)	—	—	(3,937)	—	(3,937)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(44)	(44)
Share repurchase program[b]	—	—	(822)	—	—	—	(822)	—	(822)
Share-based payment plans:									
• Exercise of stock options[b]	2	49	—	—	—	—	51	—	51
• Issuance of restricted shares and vesting of existing restricted shares[b][d]	3	(3)	126	(126)	—	—	—	—	—
• Employee share ownership plan	5	169	—	—	—	—	174	—	174
• Value of services obtained from employees	—	—	—	—	274	—	274	—	274
• Tax effects of the exercise of stock options	—	—	—	—	1	—	1	—	1
Other changes arising from issuance of restricted shares[c]	—	—	—	2	—	—	2	—	2
Balance at December 31, 2020	**2,518**	**362**	**(705)**	**60,149**	**4,138**	**(3,356)**	**63,106**	**146**	**63,252**

Consolidated statements of changes in equity

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
Balance at January 1, 2021[a]	**2,518**	**362**	**(705)**	**60,149**	**4,138**	**(3,356)**	**63,106**	**146**	**63,252**
Other comprehensive income for the period	—	—	—	797	—	2,499	3,296	11	3,307
Net income for the period	—	—	—	6,223	—	—	6,223	56	6,279
Comprehensive income for the period	**—**	**—**	**—**	**7,020**	**—**	**2,499**	**9,519**	**67**	**9,586**
Dividend paid out of 2020 earnings (€3.20 per share)	—	—	—	(4,008)	—	—	(4,008)	—	(4,008)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(49)	(49)
Share repurchase program[b]	—	—	(382)	—	—	—	(382)	—	(382)
Share-based payment plans:									
• Exercise of stock options[b]	—	11	—	—	—	—	11	—	11
• Issuance of restricted shares and vesting of existing restricted shares[b][d]	4	(4)	148	(148)	—	—	—	—	—
• Employee share ownership plan	5	163	—	—	—	—	168	—	168
• Value of services obtained from employees	—	—	—	—	244	—	244	—	244
• Tax effects of the exercise of stock options	—	—	—	—	23	—	23	—	23
Other changes in non-controlling interests[f]	—	—	—	—	—	—	—	186	186
Balance at December 31, 2021	**2,527**	**532**	**(939)**	**63,013**	**4,405**	**(857)**	**68,681**	**350**	**69,031**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

(b) See Notes D.15.1., D.15.3., D.15.4. and D.15.5.

(c) Issuance of restricted shares to former employees of the Animal Health business and the European Generics business subsequent to the date of divestment.

(d) This line includes the use of existing shares to fulfill vested rights under restricted share plans.

(e) This line includes the impact of the settlement of a put option granted to non-controlling interests in connection with a divestment.

(f) This line includes changes in non-controlling interests arising from divestments and acquisitions.

Consolidated statements of cash flows

(€ million)	Note	2021	2020 [h]	2019 [h]
Net income attributable to equity holders of Sanofi		**6,223**	**12,294**	**2,754**
Net (income)/loss of the exchanged/held-for-exchange Animal Health business		—	—	101
Non-controlling interests	D.32.	56	36	31
Share of undistributed earnings from investments accounted for using the equity method		(15)	(339)	(192)
Depreciation, amortization and impairment of property, plant and equipment, right-of-use assets and intangible assets		3,351	3,671	7,445
Gains and losses on disposals of non-current assets, net of tax[a]		(300)	(301)	(286)
Gain on Regeneron investment arising from transaction of May 29, 2020, net of tax[f]	D.2.	—	(6,880)	—
Net change in deferred taxes		(356)	(221)	(1,772)
Net change in non-current provisions and other non-current liabilities[b]		(37)	(133)	107
Cost of employee benefits (stock options and other share-based payments)	D.15.2. - D.15.3. - D.15.8.	244	274	252
Impact of the workdown of acquired inventories remeasured at fair value	D.35.1.	4	53	3
Other profit or loss items with no cash effect on cash flows generated by operating activities[g]		(57)	(711)	(309)
Operating cash flow before changes in working capital and excluding the exchanged/held-for-exchange Animal Health business		**9,113**	**7,743**	**8,134**
(Increase)/decrease in inventories		(357)	(593)	(547)
(Increase)/decrease in accounts receivable		185	(134)	(462)
Increase/(decrease) in accounts payable		451	86	169
Net change in other current assets and other current liabilities		1,130	316	421
Net cash provided by/(used in) operating activities excluding the exchanged/held-for-exchange Animal Health business[c]		**10,522**	**7,418**	**7,715**
Acquisitions of property, plant and equipment and intangible assets	D.3. - D.4.	(2,043)	(2,083)	(1,787)
Acquisitions of consolidated undertakings and investments accounted for using the equity method[d]	D.1. - D.18.	(5,594)	(5,336)	(488)
Acquisitions of other equity investments	D.7.	(311)	(137)	(38)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax[e]		718	918	1,224
Net proceeds from sale of Regeneron shares on May 29, 2020	D.2.	—	10,370	—
Net change in other non-current assets		(68)	(113)	(94)
Net cash provided by/(used in) investing activities excluding the exchanged/held-for-exchange Animal Health business		**(7,298)**	**3,619**	**(1,183)**
Net cash inflow from the exchange of the Animal Health business for BI's Consumer Healthcare business		**—**	**—**	**154**
Issuance of Sanofi shares	D.15.1.	186	203	162
Dividends paid:				
• to shareholders of Sanofi		(4,008)	(3,937)	(3,834)
• to non-controlling interests		(48)	(44)	(14)
Payments received/(made) on changes of ownership interest in a subsidiary without loss of control		—	—	(7)
Additional long-term debt contracted	D.17.1.	—	2,019	1,997
Repayments of long-term debt	D.17.1.	(2,241)	(3,952)	(2,067)
Repayments of lease liabilities		(149)	(234)	(267)
Net change in short-term debt and other financial instruments[i]		(414)	282	(154)
Acquisitions of treasury shares	D.15.4.	(382)	(822)	(9)
Net cash provided by/(used in) financing activities excluding the exchanged/held-for-exchange Animal Health business		**(7,056)**	**(6,485)**	**(4,193)**
Impact of exchange rates on cash and cash equivalents		**15**	**(64)**	**9**
Net change in cash and cash equivalents		**(3,817)**	**4,488**	**2,502**
Cash and cash equivalents, beginning of period		**13,915**	**9,427**	**6,925**
Cash and cash equivalents, end of period	**D.13.**	**10,098**	**13,915**	**9,427**

(a) Includes non-current financial assets.
(b) This line item includes contributions paid to pension funds (see Note D.19.1.).

(c) Including:

	2021	2020	2019
• Income tax paid	(1,280)	(2,051)	(1,695)
• Interest paid	(334)	(315)	(379)
• Interest received	3	37	92
• Dividends received from non-consolidated entities	2	—	—

(d) This line item includes payments made in respect of contingent consideration identified and recognized as a liability in business combinations. For 2021, it includes the net cash outflows on the acquisitions of Kymab, Kiadis, Tidal, Translate Bio, Kadmon and Origimm (see Note D.1.). For 2020, it includes the net cash outflows on the acquisitions of Synthorx and Principia (see Note D.2.1.).

(e) This line item includes proceeds from disposals of investments in consolidated entities and of other non-current financial assets. For 2021, it includes in particular the divestment of two activities relating to certain established prescription products for a total selling price (before taxes) of €187 million, and the divestment of certain Consumer Healthcare products for a selling price (before taxes) of €109 million. For 2020, it includes the sale to Baxter of operations relating to Sepraﬁlm® for a selling price (before taxes) of €311 million and the divestment of certain established prescription products for €97 million (before taxes), plus contingent consideration of €167 million (before taxes) relating to a past divestment. For 2019, it includes the proceeds from the divestments of Sanofi's entire equity interests in Alnylam for €706 million and in MyoKardia for €118 million (see Note D.7.1.).

(f) The gain on the sale of Regeneron shares is presented net of taxes, including deferred taxes of €115 million.

(g) This line item mainly comprises unrealized foreign exchange gains and losses arising on the remeasurement of monetary items in non-functional currencies and on instruments used to hedge such items.

(h) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

(i) This line item includes realized foreign exchange differences on (i) cash and cash equivalents in non-functional currencies (primarily the US dollar) and (ii) derivative instruments used to manage such cash and cash equivalents.

Notes to the Consolidated Financial Statements

Introduction

Sanofi, together with its subsidiaries (collectively "Sanofi", "the Group" or "the Company"), is a global healthcare leader engaged in the research, development and marketing of therapeutic solutions focused on patient needs.

Sanofi is listed in Paris (Euronext: SAN) and New York (Nasdaq: SNY).

The consolidated financial statements for the year ended December 31, 2021, and the notes thereto, were signed off by the Sanofi Board of Directors on February 3, 2022.

A/ Basis of preparation

A.1. International financial reporting standards (IFRS)

The consolidated financial statements cover the twelve-month periods ended December 31, 2021, 2020 and 2019.

In accordance with Regulation No. 1606/2002 of the European Parliament and Council of July 19, 2002 on the application of international accounting standards, Sanofi has presented its consolidated financial statements in accordance with IFRS since January 1, 2005. The term "IFRS" refers collectively to international accounting and financial reporting standards (IASs and IFRSs) and to interpretations of the interpretations committees (SIC and IFRIC) with mandatory application as of December 31, 2021.

The consolidated financial statements of Sanofi as of December 31, 2021 have been prepared in compliance with IFRS as issued by the International Accounting Standards Board (IASB) and with IFRS as endorsed by the European Union as of December 31, 2021.

IFRS as endorsed by the European Union as of December 31, 2021 are available under the heading "IFRS Financial Statements" via the following web link:

https://www.efrag.org/Endorsement.

The consolidated financial statements have been prepared in accordance with the IFRS general principles of fair presentation, going concern, accrual basis of accounting, consistency of presentation, materiality, and aggregation.

A.2. New standards, amendments and interpretations

A.2.1. New standards applicable from January 1, 2021

On March 31, 2021, the IASB issued "COVID-19-Related Rent Concessions beyond June 30, 2021", an amendment to IFRS 16 effective from August 31, 2021 onwards. The amendment enables lessees, subject to certain conditions, to opt out of the requirement to determine whether a COVID-19-related rent concession is a lease modification. Application of this amendment had no material impact on Sanofi.

In its March 2021 update, the IFRS IC published a final agenda decision clarifying how to account for costs of configuring or customising a supplier's application software in a Software as a Service (SaaS) arrangement, which requires such costs to be recognized as an expense. Applying that decision has resulted in a change in accounting policy, the effects of which have been reflected retrospectively in accordance with IAS 8 (Accounting Policies, Changes in Accounting Estimates and Errors). Consequently, the previously published periods have been adjusted, with the impact of first-time application reflected as from January 1, 2019, the beginning of the earliest comparative financial period presented. The adjustment as of that date represented a negative amount of €31 million, with the opposite entry recognized in equity. The table below shows the impacts on line items in the consolidated balance sheet affected by this change in accounting policy for the two comparative financial periods:

(€ million)	December 31, 2019	December 31, 2020
Other intangible assets [a]	(63)	(80)
Deferred tax assets	15	19
Non-current assets	**(48)**	**(61)**
Total assets	**(48)**	**(61)**
Equity attributable to equity holders of Sanofi	(48) [b]	(61) [c]
Total equity and liabilities	**(48)**	**(61)**

(a) The impact of €(80) million on Other intangible assets as of December 31, 2020 comprises:

- *an impact of €(115) million on the gross value of Other intangible assets, comprising (i) €(55) million as of January 1, 2019; (ii) €(30) million for the year ended December 31, 2019 (of which €(29) million relates to acquisitions and other increases in the period, as reflected within Acquisitions of property, plant and equipment and intangible assets in the consolidated statement of cash flows; and (iii) €(30) million in the year ended December 31, 2020 (of which €(31) million relates to acquisitions and other increases in the period, as reflected within Acquisitions of property, plant and equipment and intangible assets in the consolidated statement of cash flows;*
- *an impact of €35 million on amortization and impairment of Other intangible assets, comprising (i) €15 million as of January 1, 2019; (ii) €7 million for the year ended December 2019; and (iii) €13 million for the year ended December 31, 2020. The impacts arising in the years ended December 31, 2019 and 2020 have been reflected within Depreciation, amortization and impairment of property, plant and equipment, right-of-use assets and intangible assets in the consolidated statement of cash flows.*

(b) For the year ended December 31, 2019: includes impacts of €(22) million on income before taxes (operating income) and €(16) million on net income.

(c) For the year ended December 31, 2020: includes impacts of €(18) million on income before taxes (operating income) and €(14) million on net income.

In its April 2021 Update, the IFRS IC published a final agenda decision clarifying how to calculate the obligation relating to certain defined benefit plans under which the retirement benefit is (i) contingent on the employee being employed by the entity at the time of retirement; (ii) capped at a specified number of years of service; and (iii) linked to the employee's length of service at the date of retirement.

In that decision, the IFRS IC took the view that the obligation should be recognized only over the years of service preceding the date of retirement in respect of which the employee generates entitlement to the benefit. Applying that decision has resulted in a change in accounting policy, the effects of which have been reflected retrospectively in accordance with IAS 8 (Accounting Policies, Changes in Accounting Estimates and Errors). Consequently, the previously published periods have been adjusted, with the impact of first-time application reflected as from January 1, 2019, the beginning of the earliest comparative financial period presented. The opposite entry to the adjustment as of that date was recognized in equity. The service cost (including past service cost), interest cost and actuarial gains and losses have been adjusted, as have the related deferred taxes. The impacts of the decision are presented in Note D.19.1., "Provisions for pensions and other post-employment benefits" .

As a reminder, Sanofi early adopted in its consolidated financial statements for the year ended December 31, 2020 (with no material impact) the Phase 2 amendment to IFRS 9 relating to interest rate benchmark reform.

A.2.2. New pronouncements issued by the IASB and applicable from 2022 or later

This note describes standards, amendments and interpretations issued by the IASB that will have mandatory application in 2022 or subsequent years, and Sanofi's position regarding future application.

On May 14, 2020, the IASB issued "Reference to the Conceptual Framework", an amendment to IFRS 3; "Proceeds before Intended Use", an amendment to IAS 16; "Onerous Contracts — Cost of Fulfilling a Contract", an amendment to IAS 37; and "Annual Improvements to IFRS standards 2018-2020". Sanofi does not expect a material impact from those amendments, which are applicable at the earliest from January 1, 2022. Sanofi has not early adopted those amendments.

On January 23, 2020, the IASB issued "Classification of Liabilities as Current or Non-current", an amendment to IAS 1. On February 12, 2021, the IASB issued an amendment to IAS 1 concerning accounting policy disclosures, and an amendment to IAS 8 concerning the definition of accounting estimates. On May 7, 2021, the IASB issued an amendment to IAS 12 concerning deferred tax related to assets and liabilities arising from a single transaction. Sanofi does not expect any material impact from the application of these amendments, which are effective (subject to endorsement by the European Union) for annual reporting periods beginning on or after January 1, 2023. Sanofi will not early adopt these amendments.

A.3. Use of estimates and judgments

The preparation of financial statements requires management to make reasonable estimates and assumptions based on information available at the date of the finalization of the financial statements. Those estimates and assumptions may affect the reported amounts of assets, liabilities, revenues and expenses in the financial statements, and disclosures of contingent assets and contingent liabilities as of the date of the review of the financial statements. Examples of estimates and assumptions include:

- amounts deducted from sales for projected sales returns, chargeback incentives, rebates and price reductions (see Notes B.13. and D.23.);
- impairment of property, plant and equipment and intangible assets (see Notes B.6. and D.5.);
- the valuation of goodwill and the valuation and estimated useful life of acquired intangible assets (see Notes B.3.2., B.4., D.4. and D.5.);
- the measurement of contingent consideration receivable in connection with asset divestments (see Notes B.8.5. and D.12.) and of contingent consideration payable (see Notes B.3. and D.18.);
- the measurement of financial assets at amortized cost (see Note B.8.5.);

- the amount of post-employment benefit obligations (see Notes B.23. and D.19.1.);
- the amount of liabilities or provisions for restructuring, litigation, tax risks relating to corporate income taxes, and environmental risks (see Notes B.12., B.19., B.20., D.19. and D.22.); and
- the amount of deferred tax assets resulting from tax losses available for carry-forward and deductible temporary differences (see Notes B.22. and D.14.).

Actual results could differ from these estimates.

A.4. Hyperinflation

In 2021, Sanofi continued to account for subsidiaries based in Venezuela using the full consolidation method, on the basis that the criteria for control as specified in IFRS 10 (Consolidated Financial Statements) are still met. In 2018, following changes to the Venezuelan foreign exchange system, the “DICOM” rate was replaced by the “PETRO” rate (with a floating US dollar/bolivar parity) and the strong bolivar (“VEF”) was replaced by the sovereign bolivar (“VES”), reflecting a 1-for-100,000 devaluation. Finally, in October 2021 a new currency called the “Digital Bolivar” (VED) was introduced at a rate of 1 VED to 1,000,000 sovereign bolivars. Consequently, the contribution of the Venezuelan subsidiaries to the consolidated financial statements is immaterial.

In Argentina and Lebanon, the cumulative rate of inflation over the last three years is in excess of 100%, based on a combination of indices used to measure inflation in those countries. Consequently, Sanofi has treated Argentina (since July 1, 2018) and Lebanon (since January 1, 2020) as hyperinflationary economies, and applies IAS 29. The impact of the adjustments arising from applying IAS 29 to the financial statements of Sanofi subsidiaries in Argentina and Lebanon was immaterial as of December 31, 2021.

For Lebanon, following the emergence of the Sayfara foreign exchange platform in 2021 and the evolution of the business model of Sanofi's Lebanese subsidiary, the hyperinflation treatment has been adjusted by applying the Sayrafa rate when translating the subsidiary's financial statements in order to reflect the impact at the level of the Sanofi consolidated financial statements. The impacts of these adjustments are not material.

A.5. Withdrawal of the United Kingdom from the European Union

The withdrawal of the United Kingdom from the European Union has not had a material impact on the consolidated financial statements.

A.6. COVID-19 pandemic

As a reminder, COVID-19 – confirmed as a pandemic by the World Health Organisation on March 11, 2020 – had no major impact on the Sanofi consolidated financial statements for the year ended December 31, 2020. Specifically, the pandemic did not create any uncertainties which appreciably called into question the estimates and assumptions made by management.

From the first half of 2021, a return to normal activity levels was observed in the principal markets where Sanofi operates, which continued through the second half of the year. Sanofi will continue to monitor the situation, and to update management’s estimates and assumptions accordingly.

Effect of the COVID-19 pandemic on accounts receivable

As of December 31, 2021, Sanofi has identified nothing that would indicate a material increase in expected credit risk, especially as regards its principal customers.

Effect of the COVID-19 pandemic on the liquidity position

The COVID-19 pandemic did not have a negative impact on Sanofi’s liquidity position as of December 31, 2021.

A.7. Agreements relating to the recombinant COVID-19 vaccine candidate developed by Sanofi in collaboration with GSK

On February 18, 2020, Sanofi and the US Department of Health and Human Services extended their research and development partnership to leverage Sanofi’s previous development work on a SARS vaccine to attempt to unlock a fast path forward for developing a COVID-19 vaccine. Under the terms of the collaboration, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the US Department of Health and Human Services, is helping to fund the research and development undertaken by Sanofi.

On April 14, 2020, Sanofi and GlaxoSmithKline (GSK) entered into a collaboration agreement to develop a recombinant COVID-19 vaccine candidate, with Sanofi contributing its S-protein COVID-19 antigen (based on recombinant DNA technology) and GSK contributing its pandemic adjuvant technology. Sanofi is leading clinical development and the registration process for the vaccine.

On July 31, 2020, the recombinant COVID-19 vaccine candidate developed by Sanofi in collaboration with GSK was selected by the US government’s Operation Warp Speed (OWS) program. Under the OWS, the US government is providing funds to support further development of the vaccine, including clinical trials and scaling-up of manufacturing capacity. The agreement also provides for the supply of 100 million doses of the vaccine, with payment due at the time vaccine doses are provided.

Sanofi has recognized the funding received from the US government as a deduction from the development expenses incurred, in accordance with IAS 20 (Accounting for Government Grants and Disclosure of Government Assistance).

For 2021, the amount of government aid received from the US federal government and BARDA that was recognized as a deduction from development expenses was €147 million. For 2020, the amount of government aid received and recognized as a deduction from development expenses was immaterial.

As regards delivery of the 100 million vaccine doses, Sanofi considers this to be a contract with a customer, to be accounted for in accordance with IFRS 15 (Revenue from Contracts with Customers).

In September 2020, Sanofi and GSK signed pre-order contracts with the Canadian and UK governments and with the European Union for doses of the vaccine candidate. During 2021, Sanofi and GSK contractualized with the Canadian and UK governments and with the European Union on the number of doses ordered.

In accordance with IFRS 15 (see Note B.13.1.), Sanofi recognizes revenue when control over the product is transferred to the customer (for vaccines, transfer of control is usually determined by reference to the terms of release and acceptance of batches of vaccine). As of December 31, 2021, the total amount received by Sanofi since signature of the vaccine pre-order contracts was €319 million. In accordance with IFRS 15, those payments are customer contract liabilities (i.e. an obligation for the entity to supply goods to a customer, for which consideration has been received from the customer). They are presented within “Customer contract liabilities” in the balance sheet (see Note D.19.5.), and within “Net change in other current assets and other current liabilities” in the statement of cash flows.

On December 15, 2021, Sanofi and GSK announced positive preliminary data on their COVID-19 booster vaccine candidate and indicated that their Phase III trial was to continue, based on recommendations from an independent monitoring board. This latest phase in the development of the vaccine candidate has not altered the funding commitments made by the US government, or the pre-orders placed by Canada, the UK and the EU.

A.8. Effects of climate change

Risks associated with climate change as assessed to date, and the commitments made by Sanofi on carbon neutrality and cutting greenhouse gas emissions, do not have a material impact on the financial statements.

A.9. Creation and proposed IPO of the new EUROAPI entity

As previously announced, Sanofi is studying the possibility of an initial public offering (IPO) on Euronext Paris during the first half of 2022 of shares of the Sanofi subsidiary EUROAPI, subject to market conditions and obtaining required market authority approvals. The EUROAPI group, which was formed on completion of prior legal reorganization transactions in 2021, houses certain Sanofi group activities in the development, production and marketing of active pharmaceutical ingredients. Given the uncertainties notably around market conditions, Sanofi concluded that not all the IFRS 5 criteria for classifying the assets of the EUROAPI group within ***Assets held for sale or exchange*** in the consolidated balance sheet as of December 31, 2021 had been met.

As of December 31, 2021, EUROAPI represented approximately 1% of the total consolidated assets of the Sanofi group, mainly in the form of (i) dedicated industrial facilities at the chemicals sites included in the spin-out and (ii) inventories of the active pharmaceutical ingredients manufactured and commercialized by EUROAPI as of that date.

B/ Summary of significant accounting policies

B.1. Basis of consolidation

In accordance with IFRS 10 (Consolidated Financial Statements), the consolidated financial statements of Sanofi include the financial statements of entities that Sanofi controls directly or indirectly, regardless of the level of the equity interest in those entities. An entity is controlled when Sanofi has power over the entity, exposure or rights to variable returns from its involvement with the entity, and the ability to affect those returns through its power over the entity. In determining whether control exists, potential voting rights must be taken into account if those rights are substantive, in other words they can be exercised on a timely basis when decisions about the relevant activities of the entity are to be taken.

Entities consolidated by Sanofi are referred to as “subsidiaries”. Entities that Sanofi controls by means other than voting rights are referred to as “consolidated structured entities”.

In accordance with IFRS 11 (Joint Arrangements), Sanofi classifies its joint arrangements (i.e. arrangements in which Sanofi exercises joint control with one or more other parties) either as a joint operation or a joint venture. In the case of a joint operation, Sanofi recognizes the assets and liabilities of the operation in proportion to its rights and obligations relating to those assets and liabilities. Joint ventures are accounted for using the equity method.

Sanofi exercises joint control over a joint arrangement when decisions relating to the relevant activities of the arrangement require the unanimous consent of Sanofi and the other parties with whom control is shared.

Sanofi exercises significant influence over an entity when it has the power to participate in the financial and operating policy decisions of that entity, but does not have the power to exercise control or joint control over those policies.

In accordance with IAS 28 (Investments in Associates and Joint Ventures), the equity method is used to account for joint ventures (i.e. entities over which Sanofi exercises joint control) and for associates (i.e. entities over which Sanofi exercises significant influence).

Under the equity method, the investment is initially recognized at cost, and subsequently adjusted to reflect changes in the net assets of the associate or joint venture. IAS 28 does not specify the treatment to be adopted on first-time application of the equity method to an investee following a step acquisition. Consequently, by reference to paragraph 10 of IAS 28, Sanofi has opted to apply the cost method, whereby the carrying amount of the investment represents the sum of the historical cost amounts for each step in the acquisition. As of the date on which the equity method is first applied, goodwill (which is included in the carrying amount of the investment) is determined for each acquisition step. The same applies to subsequent increases in the percentage interest in the equity-accounted investment.

When the criteria of IFRS 5 are met, Sanofi recognizes the equity interest within the balance sheet line item ***Assets held for sale or exchange***. The equity method is not applied to equity interests that are classified as held-for-sale assets.

Transactions between consolidated companies are eliminated, as are intragroup profits.

A list of the principal companies included in the consolidation in 2021 is presented in Note F.

B.2. Foreign currency translation

B.2.1. Accounting for foreign currency transactions in the financial statements of consolidated entities

Non-current assets (other than receivables) and inventories acquired in foreign currencies are translated into the functional currency using the exchange rate prevailing at the acquisition date.

Monetary assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing at the end of the reporting period. The gains and losses resulting from foreign currency translation are recorded in the income statement. However, foreign exchange gains and losses arising from the translation of advances between consolidated subsidiaries for which settlement is neither planned nor likely to occur in the foreseeable future are recognized in equity, in the line item ***Change in currency translation differences***.

B.2.2. Foreign currency translation of the financial statements of foreign entities

Sanofi presents its consolidated financial statements in euros (€). In accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates), each subsidiary accounts for its transactions in the currency that is most representative of its economic environment (the functional currency).

All assets and liabilities are translated into euros using the exchange rate of the subsidiary’s functional currency prevailing at the end of the reporting period. Income statements are translated using a weighted average exchange rate for the period, except in the case of foreign subsidiaries in a hyperinflationary economy. The resulting currency translation difference is recognized as a separate component of equity in the consolidated statement of comprehensive income, and is recognized in the income statement only when the subsidiary is sold or is wholly or partially liquidated.

B.3. Business combinations and transactions with non-controlling interests

B.3.1. Accounting for business combinations, transactions with non-controlling interests and loss of control

Business combinations are accounted for in accordance with IFRS 3 (Business Combinations) and IFRS 10 (Consolidated Financial Statements).

Business combinations are accounted for using the acquisition method. Under this method, the acquiree's identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 (Business Combinations) are measured initially at their fair values at the date of acquisition, except for (i) non-current assets classified as held for sale (which are measured at fair value less costs to sell) and (ii) assets and liabilities that fall within the scope of IAS 12 (Income Taxes) and IAS 19 (Employee Benefits). Restructuring liabilities are recognized as a liability of the acquiree only if the acquiree has an obligation as of the acquisition date to carry out the restructuring.

The principal accounting rules applicable to business combinations and transactions with non-controlling interests include:

- acquisition-related costs are recognized as an expense on the acquisition date, as a component of ***Operating income***;
- contingent consideration is recognized in equity if the contingent payment is settled by delivery of a fixed number of the acquirer's equity instruments; otherwise, it is recognized in ***Liabilities related to business combinations***. Contingent consideration is recognized at fair value at the acquisition date irrespective of the probability of payment. If the contingent consideration was originally recognized as a financial liability, subsequent adjustments to the liability are recognized in profit or loss in the line item ***Fair value remeasurement of contingent consideration***, unless the adjustment is made within the twelve months following the acquisition date and relates to facts and circumstances existing as of that date;
- goodwill may be calculated on the basis of either (i) the entire fair value of the acquiree, or (ii) a share of the fair value of the acquiree proportionate to the interest acquired. This option is elected for each acquisition individually.

Purchase price allocations are performed under the responsibility of management, with assistance from an independent valuer in the case of major acquisitions. IFRS 3 does not specify an accounting treatment for contingent consideration arising from a business combination made by an entity prior to the acquisition of control in that entity and carried as a liability in the acquired entity's balance sheet. The accounting treatment applied by Sanofi to such a liability is to measure it at fair value as of the acquisition date and to report it in the line item ***Liabilities related to business combinations and to non-controlling interests***, with subsequent remeasurements recognized in profit or loss. This treatment is consistent with the accounting applied to contingent consideration in the books of the acquirer.

Finally, management may where it deems fit elect to apply the optional test to identify concentration of fair value permitted under IFRS 3 in order to determine whether a transaction is a business combination within the meaning of IFRS 3, or merely the acquisition of an asset or of a group of similar assets.

B.3.2. Goodwill

The excess of the cost of an acquisition over Sanofi's interest in the fair value of the identifiable assets and liabilities of the acquiree is recognized as goodwill at the date of the business combination.

Goodwill arising on the acquisition of subsidiaries is shown in a separate balance sheet line item, whereas goodwill arising on the acquisition of investments accounted for using the equity method is recorded in ***Investments accounted for using the equity method***.

Goodwill arising on foreign operations is expressed in the functional currency of the country concerned and translated into euros using the exchange rate prevailing at the end of the reporting period.

In accordance with IAS 36 (Impairment of Assets), goodwill is carried at cost less accumulated impairment (see Note B.6.).

Goodwill is tested for impairment annually and whenever events or circumstances indicate that impairment might exist. Such events or circumstances include significant changes more likely than not to have an other-than-temporary impact on the substance of the original investment.

B.4. Other intangible assets

Other intangible assets are initially measured at acquisition cost or production cost, including any directly attributable costs of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. Intangible assets are amortized on a straight line basis over their useful lives.

The useful lives of other intangible assets are reviewed at the end of each reporting period. The effect of any adjustment to useful lives is recognized prospectively as a change in accounting estimate.

Amortization of other intangible assets is recognized in the income statement within ***Amortization of intangible assets*** except for amortization charged against (i) acquired or internally-developed software and (ii) other rights of an industrial or operational nature, which is recognized in the relevant classification of expense by function.

Sanofi does not own any intangible assets with an indefinite useful life, other than goodwill.

Intangible assets (other than goodwill) are carried at cost less accumulated amortization and accumulated impairment, if any, in accordance with IAS 36 (see Note B.6.).

B.4.1. Research and development not acquired in a business combination

Internally generated research and development

Under IAS 38, research expenses are recognized in profit or loss when incurred.

Internally generated development expenses are recognized as an intangible asset if, and only if, all the following six criteria can be demonstrated: (a) the technical feasibility of completing the development project; (b) Sanofi's intention to complete the project; (c) Sanofi's ability to use the project; (d) the probability that the project will generate future economic benefits; (e) the availability of adequate technical, financial and other resources to complete the project; and (f) the ability to measure the development expenditure reliably.

Due to the risks and uncertainties relating to regulatory approval and to the research and development process, the six criteria for capitalization are usually considered not to have been met until the product has obtained marketing approval from the regulatory authorities. Consequently, internally generated development expenses arising before marketing approval has been obtained, mainly the cost of clinical trials, are generally expensed as incurred within ***Research and development expenses***.

Some industrial development expenses (such as those incurred in developing a second-generation synthesis process) are incurred after marketing approval has been obtained, in order to improve the industrial process for an active ingredient. To the extent that the six IAS 38 criteria are considered as having been met, such expenses are recognized as an asset in the balance sheet within ***Other intangible assets*** as incurred. Similarly, some clinical trials, for example those undertaken to obtain a geographical extension for a molecule that has already obtained marketing approval in a major market, may in certain circumstances meet the six capitalization criteria under IAS 38, in which case the related expenses are recognized as an asset in the balance sheet within ***Other intangible assets***.

Separately acquired research and development

Payments for separately acquired research and development are capitalized within ***Other intangible assets*** provided that they meet the definition of an intangible asset: a resource that is (i) controlled by Sanofi, (ii) expected to provide future economic benefits for Sanofi, and (iii) identifiable (i.e. it is either separable or arises from contractual or legal rights). Under paragraph 25 of IAS 38, the first condition for capitalization (the probability that the expected future economic benefits from the asset will flow to the entity) is considered to be satisfied for separately acquired research and development. Consequently, upfront and milestone payments to third parties related to pharmaceutical products for which marketing approval has not yet been obtained are recognized as intangible assets, and amortized on a straight line basis over their useful lives beginning when marketing approval is obtained.

Payments under research and development arrangements relating to access to technology or to databases, and payments made to purchase generics dossiers, are also capitalized, and amortized over the useful life of the intangible asset.

Subcontracting arrangements, payments for research and development services, and continuous payments under research and development collaborations which are unrelated to the outcome of that collaboration, are expensed over the service term.

B.4.2. Other intangible assets not acquired in a business combination

Licenses other than those related to pharmaceutical products and research projects, in particular software licenses, are capitalized at acquisition cost, including any directly attributable cost of preparing the software for its intended use. Software licenses are amortized on a straight line basis over their useful lives for Sanofi (three to five years).

Internally generated costs incurred to develop or upgrade software are capitalized if the IAS 38 recognition criteria are satisfied, and amortized on a straight line basis over the useful life of the software from the date on which the software is ready for use.

B.4.3. Other intangible assets acquired in a business combination

Other intangible assets acquired in a business combination which relate to in-process research and development and currently marketed products and are reliably measurable are identified separately from goodwill, measured at fair value, and capitalized within ***Other intangible assets*** in accordance with IFRS 3 (Business Combinations) and IAS 38 (Intangible Assets). The related deferred tax liability is also recognized if a deductible or taxable temporary difference exists.

In-process research and development acquired in a business combination is amortized on a straight line basis over its useful life from the date of receipt of marketing approval.

Rights to products currently marketed by Sanofi are amortized on a straight line basis over their useful lives, determined on the basis of cash flow forecasts which take into account the patent protection period of the marketed product.

B.5. Property, plant and equipment owned and leased

B.5.1. Property, plant and equipment owned

Property, plant and equipment is initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. The component-based approach to accounting for property, plant and equipment is applied. Under this approach, each component of an item of property, plant and equipment with a cost which is significant in relation to the total cost of the item and which has a different useful life from the other components must be depreciated separately.

After initial measurement, property, plant and equipment is carried at cost less accumulated depreciation and impairment, except for land which is carried at cost less impairment.

Subsequent costs are not recognized as assets unless (i) it is probable that future economic benefits associated with those costs will flow to Sanofi and (ii) the costs can be measured reliably.

Borrowing costs attributable to the financing of items of property, plant and equipment, and incurred during the construction period, are capitalized as part of the acquisition cost of the item.

Government grants relating to property, plant and equipment are deducted from the acquisition cost of the asset to which they relate.

The depreciable amount of items of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life.

The customary useful lives of property, plant and equipment are as follows:

Buildings	15 to 40 years
Fixtures	10 to 20 years
Machinery and equipment	5 to 15 years
Other	3 to 15 years

Useful lives and residual values of property, plant and equipment are reviewed annually. The effect of any adjustment to useful lives or residual values is recognized prospectively as a change in accounting estimate.

Depreciation of property, plant and equipment is recognized as an expense in the income statement, in the relevant classification of expense by function.

B.5.2. Property, plant and equipment leased

Effective from January 1, 2019 leases contracted by Sanofi have been accounted for in accordance with IFRS 16 (Leases). Sanofi recognizes a right-of-use asset and a lease liability for all of its lease contracts, except for (i) leases relating to low-value assets and (ii) short-term leases (12 months or less). Payments made in respect of leases not recognized on the balance sheet are recognized as an operating expense on a straight line basis over the lease term.

On commencement of a lease, the liability for future lease payments is discounted at the incremental borrowing rate, which is a risk-free rate adjusted to reflect the specific risk profile of each Sanofi entity. Because lease payments are spread over the lease term, Sanofi applies a discount rate based on the duration of those payments.

The payments used to determine the liability for future lease payments exclude non-lease components, but include fixed payments that Sanofi expects to make to the lessor over the estimated lease term.

After commencement of the lease, the liability for future lease payments is reduced by the amount of the lease payments made, and increased to reflect interest on the liability. In the event of a reassessment or modification of future lease payments, the lease liability is remeasured. The right-of-use asset – which is initially measured at cost including direct costs of the lessee, prepayments made at or prior to the commencement date, less lease incentives received and restoration costs – is depreciated on a straight line basis over the lease term, and tested for impairment as required.

Sanofi recognizes deferred taxes in respect of right-of-use assets and lease liabilities.

Leasehold improvements are depreciated over their economic life, which is capped at the lease term as determined under IFRS 16.

B.6. Impairment of property, plant and equipment, intangible assets, and investments accounted for using the equity method

B.6.1. Impairment of property, plant and equipment and intangible assets

In accordance with IAS 36 (Impairment of Assets), assets that generate separate cash flows and assets included in cash-generating units (CGUs) are assessed for impairment when events or changes in circumstances indicate that the asset or CGU may be impaired. A CGU is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets.

Under IAS 36, each CGU or group of CGUs to which goodwill is allocated must (i) represent the lowest level within the entity at which the goodwill is monitored for internal management purposes, and (ii) not be larger than an operating segment determined in accordance with IFRS 8 (Operating Segments), before application of the IFRS 8 aggregation criteria (see Note B.26.).

Quantitative and qualitative indications of impairment (primarily relating to the status of the research and development portfolio, pharmacovigilance, patent litigation, and the launch of competing products) are reviewed at the end of each reporting period. If there is any internal or external indication of impairment, Sanofi estimates the recoverable amount of the asset or CGU.

Other intangible assets not yet available for use (such as capitalized in-process research and development), and CGUs or groups of CGUs that include goodwill, are tested for impairment annually whether or not there is any indication of impairment, and more frequently if any event or circumstance indicates that they might be impaired. Such assets are not amortized.

When there is an internal or external indication of impairment, Sanofi estimates the recoverable amount of the asset and recognizes an impairment loss if the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of the asset is the higher of its fair value less costs to sell or its value in use. To determine value in use, Sanofi uses estimates of future cash flows generated by the asset or CGU, prepared using the same methods as those used in the initial measurement of the asset or CGU on the basis of medium-term strategic plans.

In the case of goodwill, estimates of future cash flows are based on a five-year strategic plan, an extrapolation of the cash flows over a further five-year period, and a terminal value. In the case of other intangible assets, the period used is based on the economic life of the asset.

Estimated cash flows are discounted at long-term market interest rates that reflect the best estimate by Sanofi of the time value of money, the risks specific to the asset or CGU, and economic conditions in the geographical regions in which the business activity associated with the asset or CGU is located.

Certain assets and liabilities that are not directly attributable to a specific CGU are allocated between CGUs on a basis that is reasonable, and consistent with the allocation of the corresponding goodwill.

Impairment losses arising on property, plant and equipment, on software and on certain rights are recognized in the relevant classification of expense by function.

Impairment losses arising on other intangible assets are recognized within ***Impairment of intangible assets*** in the income statement.

B.6.2. Impairment of investments accounted for using the equity method

In accordance with IAS 28 (Investments in Associates and Joint Ventures), Sanofi determines whether investments accounted for using the equity method may be impaired based on indicators such as default in contractual payments, significant financial difficulties, probability of bankruptcy, or a prolonged or significant decline in quoted market price. If an investment is impaired, the amount of the impairment loss is determined by applying IAS 36 (see Note B.6.1.) and recognized in ***Share of profit/(loss) from investments accounted for using the equity method***.

B.6.3. Reversals of impairment losses charged against property, plant and equipment, intangible assets, and investments accounted for using the equity method

At the end of each reporting period, Sanofi assesses whether events or changes in circumstances indicate that an impairment loss recognized in a prior period in respect of an asset (other than goodwill) or an investment accounted for using the equity method can be reversed. If this is the case, and the recoverable amount as determined based on the revised estimates exceeds the carrying amount of the asset, Sanofi reverses the impairment loss only to the extent of the carrying amount that would have been determined had no impairment loss been recognized for the asset.

Reversals of impairment losses in respect of other intangible assets are recognized within the income statement line item ***Impairment of intangible assets***, while reversals of impairment losses in respect of investments accounted for using the equity method are recognized within the income statement line item ***Share of profit/(loss) from investments accounted for using the equity method***. Impairment losses taken against goodwill are never reversed, unless the goodwill is part of the carrying amount of an investment accounted for using the equity method.

B.7. Assets held for sale or exchange and liabilities related to assets held for sale or exchange

In accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations), non-current assets and groups of assets are classified as held for sale in the balance sheet if their carrying amount will be recovered principally through a sale transaction rather than through continuing use. Within the meaning of IFRS 5, the term “sale” also includes exchanges for other assets.

Non-current assets or asset groups held for sale must be available for immediate sale in their present condition, subject only to terms that are usual and customary for sales of such assets, and a sale must be highly probable. Criteria used to determine whether a sale is highly probable include:

- the appropriate level of management must be committed to a plan to sell;
- an active program to locate a buyer and complete the plan must have been initiated;
- the asset must be actively marketed for sale at a price that is reasonable in relation to its current fair value;
- completion of the sale should be foreseeable within the twelve months following the date of reclassification to ***Assets held for sale or exchange***; and
- actions required to complete the plan should indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn.

Before initial reclassification of the non-current asset (or asset group) to ***Assets held for sale or exchange***, the carrying amounts of the asset (or of all the assets and liabilities in the asset group) must be measured in accordance with the applicable standards.

Subsequent to reclassification to ***Assets held for sale or exchange***, the non-current asset (or asset group) is measured at the lower of carrying amount or fair value less costs to sell, with any write-down recognized by means of an impairment loss. Once a non-current asset has been reclassified as held for sale or exchange, it is no longer depreciated or amortized.

In a disposal of an equity interest leading to loss of control, all the assets and liabilities of the entity involved are classified as held-for-sale assets or liabilities within the balance sheet line items ***Assets held for sale or exchange*** or ***Liabilities related to assets held for sale or exchange***, provided that the disposal satisfies the IFRS 5 classification criteria.

The profit or loss generated by a held-for-sale asset group is reported in a separate line item in the income statement for the current period and for the comparative periods presented, provided that the asset group:

- represents a separate major line of business or geographical area of operations; or
- is part of a single coordinated plan to dispose of a separate major line of business or geographical area of operations; or
- is a subsidiary acquired exclusively with a view to resale.

In accordance with IFRS 10, transactions between companies that are held for sale or treated as discontinued operations and other consolidated companies are eliminated.

Events or circumstances beyond Sanofi's control may extend the period to complete the sale or exchange beyond one year without precluding classification of the asset (or disposal group) in ***Assets held for sale or exchange*** provided that there is sufficient evidence that Sanofi remains committed to the planned sale or exchange. Finally, in the event of changes to a plan of sale that requires an asset no longer to be classified as held for sale, IFRS 5 specifies the following treatment:

- the assets and liabilities previously classified as held for sale are reclassified to the appropriate balance sheet line items, with no restatement of comparative periods;
- each asset is measured at the lower of (a) its carrying amount before the asset was reclassified as held for sale, adjusted for any depreciation, amortization or revaluation that would have been recognized if the asset had not been reclassified as held for sale, or (b) its recoverable amount at the date of reclassification;
- the backlog of depreciation, amortization and impairment not recognized while non-current assets were classified as held for sale must be reported in the same income statement line item that was used to report impairment losses arising on initial reclassification of assets as held for sale and gains or losses arising on the sale of such assets. In the consolidated income statement, those impacts are reported within the line item ***Other gains and losses, and litigation***;
- the net income of a business previously classified as discontinued or as held for sale or exchange and reported on a separate line in the income statement must be reclassified and included in net income from continuing operations, for all periods presented;
- in addition, segment information relating to the income statement and the statement of cash flows (acquisitions of non-current assets) must be disclosed in the notes to the financial statements in accordance with IFRS 8 (Operating Segments), and must also be restated for all prior periods presented.

B.8. Financial instruments

B.8.1. Non-derivative financial assets

In accordance with IFRS 9 (Financial Instruments) and IAS 32 (Financial Instruments: Presentation), Sanofi has adopted the classification of non-derivative financial assets described below. The classification used depends on (i) the characteristics of the contractual cash flows (i.e. whether they represent interest or principal) and (ii) the business model for managing the asset applied at the time of initial recognition.

Financial assets at fair value through other comprehensive income

These mainly comprise:

- quoted and unquoted equity investments that Sanofi does not hold for trading purposes and that management has designated at "fair value through other comprehensive income" on initial recognition. Gains and losses arising from changes in fair value are recognized in equity within the statement of comprehensive income in the period in which they occur. When such instruments are derecognized, the previously-recognized changes in fair value remain within ***Other comprehensive income***, as does the gain or loss on divestment. Dividends received are recognized in profit or loss for the period, within the line item ***Financial income***; and
- debt instruments whose contractual cash flows represent payments of interest or repayments of principal, and which are managed with a view to collecting cash flows and selling the asset. Gains and losses arising from changes in fair value are recognized in equity within the statement of comprehensive income in the period in which they occur. When such assets are derecognized, the cumulative gains and losses previously recognized in equity are reclassified to profit or loss for the period within the line items ***Financial income*** or ***Financial expenses***.

Financial assets at fair value through profit or loss

These mainly comprise:

- contingent consideration already carried in the books of an acquired entity or granted in connection with a business combination;
- instruments whose contractual cash flows represent payments of interest and repayments of principal, which are managed with a view to selling the asset;
- instruments that management has designated at "fair value through profit or loss" on initial recognition; and
- quoted and unquoted equity investments: equity instruments that are not held for trading and which management did not designate at "fair value through other comprehensive income" on initial recognition, and instruments that do not meet the IFRS definition of "equity instruments".

Gains and losses arising from changes in fair value are recognized in profit or loss within the line items ***Financial income*** or ***Financial expenses***. Dividends received are recognized in profit or loss for the period, within the line item ***Financial income***.

Fair value of equity investments in unquoted entities

On initial recognition of an equity investment in an entity not quoted in an active market, the fair value of the investment is the acquisition cost. Cost ceases to be a representative measure of the fair value of an unquoted equity investment when Sanofi identifies significant changes in the investee, or in the environment in which it operates. In such cases, an internal valuation is carried out, based mainly on growth forecasts or by reference to similar transactions contracted with third parties.

Financial assets measured at amortized cost

Financial assets at amortized cost comprise instruments whose contractual cash flows represent payments of interest and repayments of principal and which are managed with a view to collecting cash flows. The main assets in this category are loans and receivables. They are presented within the line items ***Other non-current assets***, ***Other current assets***, ***Accounts receivable*** and ***Cash and cash equivalents***. Loans with a maturity of more than 12 months are presented in "Long-term loans and advances" within ***Other non-current assets***. These financial assets are measured at amortized cost using the effective interest method.

Impairment of financial assets measured at amortized cost

The main assets involved are accounts receivable. Accounts receivable are initially recognized at the amount invoiced to the customer. Impairment losses on trade accounts receivable are estimated using the expected loss method, in order to take account of the risk of payment default throughout the lifetime of the receivables. The expected credit loss is estimated collectively for all accounts receivable at each reporting date using an average expected loss rate, determined primarily on the basis of historical credit loss rates. However, that average expected loss rate may be adjusted if there are indications of a likely significant increase in credit risk. If a receivable is subject to a known credit risk, a specific impairment loss is recognized for that receivable. The amount of expected losses is recognized in the balance sheet as a reduction in the gross amount of accounts receivable. Impairment losses on accounts receivable are recognized within ***Selling and general expenses*** in the income statement.

B.8.2. Derivative instruments

Derivative instruments that do not qualify for hedge accounting are initially and subsequently measured at fair value, with changes in fair value recognized in the income statement in ***Other operating income*** or in ***Financial income*** or ***Financial expenses***, depending on the nature of the underlying economic item which is hedged.

Derivative instruments that qualify for hedge accounting are measured using the policies described in Note B.8.3. below.

IFRS 13 (Fair Value Measurement) requires counterparty credit risk to be taken into account when measuring the fair value of financial instruments. That risk is estimated on the basis of observable, publicly-available statistical data.

Policy on offsetting

In order for a financial asset and a financial liability to be presented as a net amount in the balance sheet under IAS 32, there must be:

(a) a legally enforceable right to offset; and

(b) the intention either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

B.8.3. Hedging

As part of its overall market risk management policy, Sanofi enters into various hedging transactions involving derivative or non-derivative instruments; these may include forward contracts, currency swaps or options, interest rate swaps or options, cross-currency swaps, and debt placings or issues.

Such financial instruments are designated as hedging instruments and recognized using the hedge accounting principles of IFRS 9 when (a) there is formal designation and documentation of the hedging relationship, of how the effectiveness of the hedging relationship will be assessed, and of the underlying market risk management objective and strategy; (b) the hedged item and the hedging instrument are eligible for hedge accounting; and (c) there is an economic relationship between the hedged item and the hedging instrument, defined on the basis of a hedge ratio that is consistent with the underlying market risk management strategy, and the residual credit risk does not dominate the value changes that result from that economic relationship.

Fair value hedge

A fair value hedge is a hedge of the exposure to changes in fair value of an asset, liability or firm commitment that is attributable to one or more risk components and could affect profit or loss.

Changes in fair value of the hedging instrument and changes in fair value of the hedged item attributable to the hedged risk components are generally recognized in the income statement, within ***Other operating income*** for hedges related to operating activities, or within ***Financial income*** or ***Financial expenses*** for hedges related to investing or financing activities.

Cash flow hedge

A cash flow hedge is a hedge of the exposure to variability in cash flows from an asset, liability or highly probable forecast transaction that is attributable to one or more risk components and could affect profit or loss.

Changes in fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement within ***Other operating income*** for hedges related to operating activities, and within ***Financial income*** or ***Financial expenses*** for hedges related to investing or financing activities.

Cumulative changes in fair value of the hedging instrument previously recognized in equity are reclassified to the income statement when the hedged transaction affects profit or loss. Those reclassified gains and losses are recognized within ***Other operating income*** for hedges related to operating activities, and within ***Financial income*** or ***Financial expenses*** for hedges related to investing or financing activities.

When a forecast transaction results in the recognition of a non-financial asset or liability, cumulative changes in the fair value of the hedging instrument previously recognized in equity are incorporated in the initial carrying amount of that asset or liability.

When the hedging instrument expires or is sold, terminated or exercised, the cumulative gain or loss previously recognized in equity remains separately recognized in equity and is not reclassified to the income statement, or recognized as an adjustment to the initial cost of the related non-financial asset or liability, until the forecast transaction occurs. However, if Sanofi no longer expects the forecast transaction to occur, the cumulative gain or loss previously recognized in equity is recognized immediately in profit or loss.

Hedge of a net investment in a foreign operation

In a hedge of a net investment in a foreign operation, changes in the fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement within ***Financial income*** or ***Financial expenses***. When the investment in the foreign operation is sold, the changes in the fair value of the hedging instrument previously recognized in equity are reclassified to the income statement within ***Financial income*** or ***Financial expenses***.

Cost of hedging

As part of its market risk management policy, Sanofi may designate currency options or interest rate options as hedging instruments, the effectiveness of which is measured on the basis of changes in intrinsic value. In such cases, the time value of the option is treated as a hedging cost and accounted for as follows:

- if the option includes a component that is not aligned on the critical features of the hedged item, the corresponding change in the time value is taken to profit or loss;
- otherwise, the change in the time value is taken to equity within the statement of comprehensive income, and then:
  - if the hedged item is linked to a transaction that results in the recognition of a financial asset or liability, the change in the time value is reclassified to profit or loss symmetrically with the hedged item, or
  - if the hedged item is linked to a transaction that results in the recognition of a non-financial asset or liability, the change in the time value is incorporated in the initial carrying amount of that asset or liability, or
  - if the hedged item is linked to a period of time, the change in time value is reclassified to profit or loss on a straight line basis over the life of the hedging relationship.

In the case of forward contracts and foreign exchange swaps, and of cross-currency swaps that qualify for hedge accounting on the basis of changes in spot rates, Sanofi may elect for each transaction to use the option whereby the premium/discount or foreign currency basis spread are treated in the same way as the time value of an option.

Discontinuation of hedge accounting

Hedge accounting is discontinued when the eligibility criteria are no longer met (in particular, when the hedging instrument expires or is sold, terminated or exercised), or if there is a change in the market risk management objective of the hedging relationship.

B.8.4. Non-derivative financial liabilities

Borrowings and debt

Bank borrowings and debt instruments are initially measured at fair value of the consideration received, net of directly attributable transaction costs.

Subsequently, they are measured at amortized cost using the effective interest method. All costs related to the issuance of borrowings or debt instruments, and all differences between the issue proceeds net of transaction costs and the value on redemption, are recognized within ***Financial expenses*** in the income statement over the term of the debt using the effective interest method.

Liabilities related to business combinations and to non-controlling interests

These line items record the fair value of (i) contingent consideration payable in connection with business combinations and (ii) commitments to buy out equity holders of subsidiaries, including put options granted to non-controlling interests.

Adjustments to the fair value of commitments to buy out equity holders of subsidiaries, including put options granted to non-controlling interests, are recognized in equity.

Other non-derivative financial liabilities

Other non-derivative financial liabilities include trade accounts payable, which are measured at fair value (which in most cases equates to face value) on initial recognition, and subsequently at amortized cost.

B.8.5. Fair value of financial instruments

Under IFRS 13 (Fair Value Measurement) and IFRS 7 (Financial Instruments: Disclosures), fair value measurements must be classified using a hierarchy based on the inputs used to measure the fair value of the instrument. This hierarchy has three levels:

(a) level 1: quoted prices in active markets for identical assets or liabilities (without modification or repackaging);

(b) level 2: quoted prices in active markets for similar assets and liabilities, or valuation techniques in which all important inputs are derived from observable market data; and

(c) level 3: valuation techniques in which not all important inputs are derived from observable market data.

The table below shows the disclosures required under IFRS 7 relating to the measurement principles applied to financial instruments.

					Method used to determine fair value		
						Market data	
Note	Type of financial instrument	Measurement principle	Level in fair value hierarchy	Valuation technique	Valuation model	Exchange rate	Interest rate
D.7.	Financial assets measured at fair value (quoted equity instruments)	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets measured at fair value (quoted debt instruments)	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets measured at fair value (unquoted equity instruments)	Fair value	3	Cost / Approach based on comparables	If cost ceases to be a representative measure of fair value, an internal valuation is carried out, based mainly on comparables.		
D.7.	Financial assets measured at fair value (contingent consideration receivable)	Fair value	3	Revenue-based approach	The fair value of contingent consideration receivable is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note D.7.3.		
D.7.	Financial assets measured at fair value held to meet obligations under post-employment benefit plans	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets designated at fair value held to meet obligations under deferred compensation plans	Fair value	1	Market value	Quoted market price		N/A
D.7.	Long-term loans and advances and other non-current receivables	Amortized cost	N/A	N/A	The amortized cost of long-term loans and advances and other non-current receivables at the end of the reporting period is not materially different from their fair value.		
D.13.	Investments in mutual funds	Fair value	1	Market value	Net asset value		N/A
D.13.	Negotiable debt instruments, commercial paper, instant access deposits and term deposits	Amortized cost	N/A	N/A	Because these instruments have a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as disclosed in the notes to the consolidated financial statements.		
D.17.1.	Debt	Amortized cost[(a)]	N/A	N/A	In the case of debt with a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as reported in the notes to the consolidated financial statements. For debt with a maturity of more than 3 months, fair value as reported in the notes to the consolidated financial statements is determined either by reference to quoted market prices at the end of the reporting period (quoted instruments) or by discounting the future cash flows based on observable market data at the end of the reporting period (unquoted instruments).		
D.17.2.	Lease liabilities	Amortized cost	N/A	N/A	The liability for future lease payments is discounted using the incremental borrowing rate.		
D.20.	Forward currency contracts	Fair value	2		Present value of future cash flows	Mid Market	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon
D.20.	Interest rate swaps	Fair value	2	Revenue-based approach	Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon
D.20.	Cross-currency swaps	Fair value	2		Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon
D.18.	Liabilities related to business combinations and to non-controlling interests (CVRs)	Fair value	1	Market value	Quoted market price		
D.18.	Liabilities related to business combinations and to non-controlling interests (other than CVRs)	Fair value	3	Revenue-based approach	Under IAS 32, contingent consideration payable in a business combination is a financial liability. The fair value of such liabilities is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note B.8.4.		

(a) In the case of debt designated as a hedged item in a fair value hedging relationship, the carrying amount in the consolidated balance sheet includes changes in fair value attributable to the hedged risk(s).

The fair value of the Dexcom equity derivatives (see Note D.20.c.) is classified as Level 2 because the valuation is based on a generally accepted technique (the Black & Scholes model) that uses inputs from directly observable market parameters (share price, risk free rate and implied volatility).

B.8.6. Derecognition of financial instruments

Financial assets are derecognized when the contractual rights to cash flows from the asset have ended or have been transferred and when Sanofi has transferred substantially all the risks and rewards of ownership of the asset. If Sanofi has neither transferred nor retained substantially all the risks and rewards of ownership of a financial asset, it is derecognized if Sanofi does not retain control of the asset.

A financial liability is derecognized when Sanofi's contractual obligations in respect of the liability are discharged, cancelled or extinguished.

B.8.7. Risks relating to financial instruments

Market risks in respect of non-current financial assets, cash equivalents, derivative instruments and debt are described in the discussions of risk factors presented in Item 3.D. and Item 11. of Sanofi's Annual Report on Form 20-F for 2021.

Credit risk is the risk that customers may fail to pay their debts. For a description of credit risk, refer to "We are subject to the risk of non-payment by our customers" within Item 3.D. and Item 11. of Sanofi's Annual Report on Form 20-F for 2021.

B.9. Inventories

Inventories are measured at the lower of cost or net realizable value. Cost is calculated using the weighted average cost method or the first-in, first-out method, depending on the nature of the inventory.

The cost of finished goods inventories includes costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

During the launch phase of a new product, any inventories of that product are written down to zero pending regulatory approval, other than in specific circumstances which make it possible to estimate that there is a high probability at the end of the reporting period that the carrying amount of the inventories will be recoverable. The write-down is reversed once it becomes highly probable that marketing approval will be obtained.

B.10. Cash and cash equivalents

Cash and cash equivalents as shown in the consolidated balance sheet and statement of cash flows comprise cash, plus liquid short-term investments that are readily convertible into cash and are subject to an insignificant risk of changes in value in the event of movements in interest rates.

B.11. Treasury shares

In accordance with IAS 32, Sanofi treasury shares are deducted from equity, irrespective of the purpose for which they are held. No gain or loss is recognized in the income statement on the purchase, sale, impairment or cancellation of treasury shares.

B.12. Provisions for risks

In accordance with IAS 37 (Provisions, Contingent Liabilities and Contingent Assets), Sanofi records a provision when it has a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources.

If the obligation is expected to be settled more than twelve months after the end of the reporting period, or has no definite settlement date, the provision is recorded within Non-current provisions and other non-current liabilities.

Provisions relating to the insurance programs in which Sanofi's captive insurance company participates are based on risk exposure estimates calculated by management, with assistance from independent actuaries, using IBNR (Incurred But Not Reported) techniques. Those techniques use past claims experience, within Sanofi and in the market, to estimate future trends in the cost of claims.

Contingent liabilities are not recognized, but are disclosed in the notes to the financial statements unless the possibility of an outflow of economic resources is remote.

Sanofi estimates provisions on the basis of events and circumstances related to present obligations at the end of the reporting period and of past experience, and to the best of management's knowledge at the date of preparation of the financial statements.

Reimbursements offsetting the probable outflow of resources are recognized as assets only if it is virtually certain that they will be received. Contingent assets are not recognized.

Restructuring provisions are recognized if Sanofi has a detailed, formal restructuring plan at the end of the reporting period and has announced its intention to implement this plan to those affected by it.

No provisions are recorded for future operating losses.

Sanofi records non-current provisions for certain obligations, such as legal or constructive obligations, where an outflow of resources is probable and the amount of the outflow can be reliably estimated.

In the case of environmental risks, including at sites where operations are ongoing, Sanofi recognizes a provision where there is a violation of integrity in respect of human health or the environment resulting from past contamination at a site that requires remediation. The amount of the provision is a best estimate of the future expenditures to be incurred on the remediation plan.

Where the effect of the time value of money is material, those provisions are measured at the present value of the expenditures expected to be required to settle the obligation, calculated using a discount rate that reflects an estimate of the time value of money and the risks specific to the obligation.

Increases in provisions to reflect the effects of the passage of time are recognized within ***Financial expenses***.

B.13. Revenue recognition

B.13.1. Net sales

Revenue arising from the sale of goods is presented in the income statement within ***Net sales***. Net sales comprise revenue from sales of pharmaceutical products, consumer healthcare products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Analyses of net sales are provided in Note D.35.1. “Segment Information”.

In accordance with IFRS 15 (Revenue from Contracts with Customers), such revenue is recognized when Sanofi transfers control over the product to the customer; control of an asset refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from that asset. For the vast majority of contracts, revenue is recognized when the product is physically transferred, in accordance with the delivery and acceptance terms agreed with the customer.

For contracts entered into by Sanofi Pasteur, transfer of control is usually determined by reference to the terms of release (immediate or deferred) and acceptance of batches of vaccine.

In the case of contracts with distributors, Sanofi does not recognize revenue when the product is physically transferred to the distributor if the products are sold on consignment, or if the distributor acts as agent. In such cases, revenue is recognized when control is transferred to the end customer, and the distributor’s commission is presented within the line item ***Selling and general expenses*** in the income statement.

The amount of revenue recognized reflects the various types of price reductions or rights of return offered by Sanofi to its customers on certain products. Such price reductions and rights of return qualify as variable consideration under IFRS 15.

In particular, products sold in the United States are covered by various Government and State programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. Returns, discounts, incentives and rebates, as described above, are recognized in the period in which the underlying sales are recognized as a reduction of gross sales.

These amounts are calculated as follows:

- the amount of chargeback incentives is estimated on the basis of the relevant subsidiary’s standard sales terms and conditions, and in certain cases on the basis of specific contractual arrangements with the customer;
- the amount of rebates based on attainment of sales targets is estimated and accrued as each of the underlying sales transactions is recognized;
- the amount of price reductions under Government and State programs, largely in the United States, is estimated on the basis of the specific terms of the relevant regulations or agreements, and accrued as each of the underlying sales transactions is recognized;
- the amount of sales returns is calculated on the basis of management’s best estimate of the amount of product that will ultimately be returned by customers. In countries where product returns are possible, Sanofi operates a returns policy that allows the customer to return products within a certain period either side of the expiry date (usually 12 months after the expiry date). The amount recognized for returns is estimated on the basis of past experience of sales returns. Sanofi also takes into account factors such as levels of inventory in its various distribution channels, product expiry dates, information about potential discontinuation of products, the entry of competing generics into the market, and the launch of over-the-counter medicines. Most product return clauses relate solely to date-expired products, which cannot be resold and are destroyed. Sanofi does not recognize a right of return asset in the balance sheet for contracts that allow for the return of time-expired products, since those products have no value.

The estimated amounts described above are recognized in the income statement within ***Net sales*** as a reduction of gross sales, and within ***Other current liabilities*** in the balance sheet. They are subject to regular review and adjustment as appropriate based on the most recent data available to management. Sanofi believes that it has the ability to measure each of the above amounts reliably, using the following factors in developing its estimates:

- the nature and patient profile of the underlying product;
- the applicable regulations or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers;
- historical data relating to similar contracts, in the case of qualitative and quantitative rebates and chargeback incentives;
- past experience and sales growth trends for the same or similar products;
- actual inventory levels in distribution channels, monitored by Sanofi using internal sales data and externally provided data;
- the shelf life of Sanofi products; and
- market trends including competition, pricing and demand.

An analysis of provisions for discounts, rebates and sales returns is provided in Note D.23.

B.13.2. Other revenues

Other revenues mainly comprise royalties received from licensing intellectual property rights to third parties; VaxServe sales of products sourced from third-party manufacturers; and revenue received under agreements for Sanofi to provide manufacturing services to third parties.

Royalties received under licensing arrangements are recognized over the period during which the underlying sales are recognized.

VaxServe is a Vaccines segment entity whose operations include the distribution within the United States of vaccines and other products manufactured by third parties. VaxServe sales of products sourced from third-party manufacturers are presented within ***Other revenues***.

B.14. Cost of sales

Cost of sales consists primarily of the industrial cost of goods sold, payments made under licensing agreements, and distribution costs. The industrial cost of goods sold includes the cost of materials, depreciation of property, plant and equipment, amortization of software, personnel costs, and other expenses attributable to production.

B.15. Research and development

Note B.4.1. “Research and development not acquired in a business combination” and Note B.4.3. “Other intangible assets acquired in a business combination” describe the principles applied to the recognition of research and development costs.

Contributions or reimbursements received from alliance partners are recorded as a reduction of ***Research and development expenses***.

B.16. Other operating income and expenses

B.16.1. Other operating income

Other operating income includes the share of profits that Sanofi is entitled to receive from alliance partners in respect of product marketing agreements. It also includes revenues generated under certain complex agreements, which may include partnership and co-promotion arrangements.

This line item also includes realized and unrealized foreign exchange gains and losses on operating activities (see Note B.8.3.), and operating gains on disposals not regarded as major disposals (see Note B.20.).

B.16.2. Other operating expenses

Other operating expenses mainly comprise the share of profits that alliance partners are entitled to receive from Sanofi under product marketing agreements.

B.17. Amortization and impairment of intangible assets

B.17.1. Amortization of intangible assets

The expenses recorded in this line item comprise amortization of product rights and other intangible assets (see Note D.4.), given that the benefit of those rights to Sanofi’s commercial, industrial and development functions cannot be separately identified.

Amortization of software, and of other rights of an industrial or operational nature, is recognized as an expense in the income statement, in the relevant line items of expense by function.

B.17.2. Impairment of intangible assets

This line item records impairment losses (other than those associated with restructuring) recognized against intangible assets (including goodwill, but excluding software and other rights of an industrial or operational nature), and any reversals of such impairment losses.

B.18. Fair value remeasurement of contingent consideration

Changes in the fair value of contingent consideration that was (i) already carried in the books of an acquired entity, or (ii) granted in connection with a business combination and initially recognized as a liability in accordance with IFRS 3, are reported in profit or loss. Such adjustments are reported separately in the income statement, in the line item ***Fair value remeasurement of contingent consideration.***

This line item also includes changes in the fair value of contingent consideration receivable in connection with a divestment and classified as a financial asset at fair value through profit or loss.

Finally, it includes the effect of the unwinding of discount, and of exchange rate movements where the asset or liability is expressed in a currency other than the functional currency of the reporting entity.

B.19. Restructuring costs and similar items

Restructuring costs are expenses incurred in connection with the transformation or reorganization of Sanofi’s operations or support functions. Such costs include collective redundancy plans, compensation to third parties for early termination of contracts, and commitments made in connection with transformation or reorganization decisions. They also include accelerated depreciation charges arising from site closures (including closures of leased sites), and losses on asset disposals resulting from such decisions.

In addition, this line item includes expenses incurred in connection with programs implemented as part of the transformation strategy announced in December 2019 (and previously in November 2015), and intended primarily to (i) deliver a global information systems solution, further supported by the implementation in 2021 of Sanofi's new digital strategy; (ii) create a standalone Consumer Healthcare

entity; and (iii) as announced on February 24, 2020, create a European leader in the production and marketing to third parties of active pharmaceutical ingredients (API).

B.20. Other gains and losses, and litigation

The line item ***Other gains and losses, and litigation*** includes the impact of material transactions of an unusual nature or amount which Sanofi believes it necessary to report separately in the income statement in order to improve the relevance of the financial statements, such as:

- gains and losses on major disposals of property, plant and equipment, of intangible assets, of assets (or groups of assets and liabilities) held for sale, or of a business within the meaning of IFRS 3, other than those considered to be restructuring costs;
- impairment losses and reversals of impairment losses on assets (or groups of assets and liabilities) held for sale, other than those considered to be restructuring costs;
- gains on bargain purchases;
- costs and provisions relating to major litigation; and
- pre-tax separation costs associated with the process of disinvesting from operations in the event of a major divestment.

B.21. Financial expenses and income

B.21.1. Financial expenses

Financial expenses mainly comprise interest charges on debt financing; negative changes in the fair value of certain financial instruments (where changes in fair value are recognized in profit or loss); realized and unrealized foreign exchange losses on financing and investing activities; impairment losses on financial instruments; and any reversals of impairment losses on financial instruments.

Financial expenses also include expenses arising from the unwinding of discount on long-term provisions, and the net interest cost related to employee benefits. This line item does not include commercial cash discounts, which are deducted from net sales.

B.21.2. Financial income

Financial income includes interest and dividend income; positive changes in the fair value of certain financial instruments (where changes in fair value are recognized in profit or loss); realized and unrealized foreign exchange gains on financing and investing activities; and gains on disposals of financial assets at fair value through profit or loss.

B.22. Income tax expense

Income tax expense includes all current and deferred taxes of consolidated companies.

Sanofi accounts for deferred taxes in accordance with IAS 12 (Income Taxes), using the methods described below:

- deferred tax assets and liabilities are recognized on taxable and deductible temporary differences, and on tax loss carry-forwards. Temporary differences are differences between the carrying amount of an asset or liability in the balance sheet and its tax base;
- French business taxes include a value added based component: “CVAE” *(Cotisation sur la Valeur Ajoutée des Entreprises)*. Given that CVAE is (i) calculated as the amount by which certain revenues exceed certain expenses and (ii) borne primarily by companies that own intellectual property rights on income derived from those rights (royalties, and margin on sales to third parties and to Sanofi entities), it is regarded as meeting the definition of income taxes specified in IAS 12, paragraph 2 (“taxes which are based on taxable profits”);
- deferred tax assets and liabilities are calculated using the tax rate expected to apply in the period when the corresponding temporary differences are expected to reverse, based on tax rates enacted or substantively enacted at the end of the reporting period;
- deferred tax assets are recognized in respect of deductible temporary differences, tax losses available for carry-forward and unused tax credits to the extent that future recovery is regarded as probable. The recoverability of deferred tax assets is assessed on a case-by-case basis, taking into account the profit forecasts contained in Sanofi’s medium-term business plan;
- a deferred tax liability is recognized for temporary differences relating to interests in subsidiaries, associates and joint ventures, except in cases where Sanofi is able to control the timing of the reversal of the temporary differences. This applies in particular when Sanofi is able to control dividend policy and it is probable that the temporary differences will not reverse in the foreseeable future;
- No deferred tax is recognized on eliminations of intragroup transfers of interests in subsidiaries, associates or joint ventures;
- each tax entity calculates its own net deferred tax position. All net deferred tax asset and liability positions are then aggregated and shown in separate line items on the relevant side of the consolidated balance sheet. Deferred tax assets and liabilities are offset only if (i) Sanofi has a legally enforceable right to offset current tax assets and current tax liabilities, and (ii) the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority;
- deferred taxes are not discounted, except implicitly in the case of deferred taxes on assets and liabilities which are already impacted by discounting. In addition, Sanofi has elected not to discount current taxes payable or receivable where the amounts in question are payable or receivable in the long term;
- withholding taxes on intragroup royalties and dividends, and on royalties and dividends collected from third parties, are accounted for as current income taxes.

In accounting for business combinations, Sanofi complies with IFRS 3 as regards the recognition of deferred tax assets after the initial accounting period. Consequently, any deferred tax assets recognized by the acquiree after the end of that period in respect of temporary differences or tax loss carry-forwards existing at the acquisition date are recognized in profit or loss.

The positions adopted by Sanofi in tax matters are based on its interpretation of tax laws and regulations. Some of those positions may be subject to uncertainty. In such cases, Sanofi assesses the amount of the tax liability on the basis of the following assumptions: that its position will be examined by one or more tax authorities on the basis of all relevant information; that a technical assessment is carried out with reference to legislation, case law, regulations, and established practice; and that each position is assessed individually (or collectively where appropriate), with no offset or aggregation between positions. Those assumptions are assessed on the basis of facts and circumstances existing at the end of the reporting period. When an uncertain tax liability is regarded as probable, it is measured on the basis of Sanofi's best estimate and recognized as a liability; uncertain tax assets are not recognized. The amount of the liability includes any penalties and late payment interest. The line item ***Income tax expense*** includes the effects of tax reassessments and tax disputes, and any penalties and late payment interest arising from such disputes that have the characteristics of income taxes within the meaning of paragraph 2 of IAS 12 ("taxes which are based on taxable profits"). Tax exposures relating to corporate income taxes are presented separately within ***Non-current income tax liabilities*** (see Note D.19.4.).

No deferred taxation is recognized on temporary differences that are liable to be subject to US global intangible low taxed income (GILTI) provisions. The related tax expense is recognized in the year in which it is declared in the tax return to the extent that it arises from the existence of non-US profits that exceed the theoretical return on investment specified in the GILTI provisions and are taxed at a rate lower than the applicable US tax rate.

In accordance with IAS 1 (Presentation of Financial Statements), current income tax assets and liabilities are presented as separate line items in the consolidated balance sheet.

B.23. Employee benefit obligations

Sanofi offers retirement benefits to employees and retirees. Such benefits are accounted for in accordance with IAS 19 (Employee Benefits).

Benefits are provided in the form of either defined contribution plans or defined benefit plans. In the case of defined contribution plans, the cost is recognized immediately in the period in which it is incurred, and equates to the amount of the contributions paid by Sanofi. For defined benefit plans, Sanofi generally recognizes its obligations to pay pensions and similar benefits to employees as a liability, based on an actuarial estimate of the rights vested or currently vesting in employees and retirees, using the projected unit credit method. Estimates are performed at least once a year, and rely on financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

Obligations relating to other post-employment benefits (healthcare and life insurance) offered by Sanofi companies to employees are also recognized as a liability based on an actuarial estimate of the rights vested or currently vesting in employees and retirees at the end of the reporting period.

Such liabilities are recognized net of the fair value of plan assets.

In the case of multi-employer defined benefit plans where plan assets cannot be allocated to each participating employer with sufficient reliability, the plan is accounted for as a defined contribution plan, in accordance with paragraph 34 of IAS 19.

The benefit cost for the period consists primarily of current service cost, past service cost, net interest cost, gains or losses arising from plan settlements not specified in the terms of the plan, and actuarial gains or losses arising from plan curtailments. Net interest cost for the period is determined by applying the discount rate specified in IAS 19 to the net liability (i.e. the amount of the obligation, net of plan assets) recognized in respect of defined benefit plans. Past service cost is recognized immediately in profit or loss in the period in which it is incurred, regardless of whether or not the rights have vested at the time of adoption (in the case of a new plan) or of amendment (in the case of an existing plan).

Actuarial gains and losses on defined benefit plans (pensions and other post-employment benefits), also referred to as "Remeasurements of the net defined benefit liability (asset)", arise as a result of changes in financial and demographic assumptions, experience adjustments, and the difference between the actual return and interest cost on plan assets. The impacts of those remeasurements are recognized in ***Other comprehensive income***, net of deferred taxes; they are not subsequently reclassifiable to profit or loss.

B.24. Share-based payment

Share-based payment expense is recognized as a component of operating income, in the relevant classification of expense by function. In measuring the expense, the level of attainment of any performance conditions is taken into account.

B.24.1. Stock option plans

Sanofi has granted a number of equity-settled share-based payment plans (stock option plans) to some of its employees. The terms of those plans may make the award contingent on the attainment of performance criteria for some of the grantees.

In accordance with IFRS 2 (Share-Based Payment), services received from employees as consideration for stock options are recognized as an expense in the income statement, with the opposite entry recognized in equity. The expense corresponds to the fair value of the stock option plans, and is charged to income on a straight-line basis over the four-year vesting period of the plan.

The fair value of stock option plans is measured at the date of grant using the Black-Scholes valuation model, taking into account the expected life of the options. The resulting expense also takes into account the expected cancellation rate of the options. The expense is adjusted over the vesting period to reflect actual cancellation rates resulting from option-holders ceasing to be employed by Sanofi.

B.24.2. Employee share ownership plans

Sanofi may offer its employees the opportunity to subscribe to reserved share issues at a discount to the reference market price. Shares awarded to employees under such plans fall within the scope of IFRS 2. Consequently, an expense is recognized at the subscription date, based on the value of the discount offered to employees.

B.24.3. Restricted share plans

Sanofi may award restricted share plans to certain of its employees. The terms of those plans may make the award contingent on the attainment of performance criteria for some of the grantees.

In accordance with IFRS 2, an expense equivalent to the fair value of such plans is recognized in profit or loss on a straight line basis over the vesting period of the plan, with the opposite entry recognized in equity. The vesting period is three years.

The fair value of restricted share plans is based on the quoted market price of Sanofi shares at the date of grant, adjusted for expected dividends during the vesting period; it also takes account of any vesting conditions contingent on stock market performance. Other vesting conditions are taken into account in the estimate of the number of shares awarded during the vesting period; that number is then definitively adjusted based on the actual number of shares awarded on the vesting date.

B.25. Earnings per share

Basic earnings per share is calculated using the weighted average number of shares outstanding during the reporting period, adjusted on a time-weighted basis from the acquisition date to reflect the number of own shares held by Sanofi. Diluted earnings per share is calculated on the basis of the weighted average number of ordinary shares, computed using the treasury stock method.

This method assumes that (i) all outstanding dilutive options and warrants are exercised, and (ii) Sanofi acquires its own shares at the quoted market price for an amount equivalent to the cash received as consideration for the exercise of the options or warrants, plus the expense arising on unamortized stock options.

B.26. Segment information

In accordance with IFRS 8 (Operating Segments), the segment information reported by Sanofi is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the chief operating decision maker. The performance of those segments is monitored individually using internal reports and common indicators. Disclosures about operating segments required under IFRS 8 are presented in Note D.35. “Segment information” to the consolidated financial statements.

Sanofi has three operating segments: Pharmaceuticals, Vaccines, and Consumer Healthcare.

The Pharmaceuticals segment comprises, for all geographical territories, the commercial operations of the following global franchises: Specialty Care (Dupixent®, Neurology & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders) and General Medicines (Diabetes, Cardiovascular & Established Prescription Products), together with research, development and production activities dedicated to the Pharmaceuticals segment. This segment also includes associates whose activities are related to pharmaceuticals. Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.2.). Consequently, the Pharmaceuticals segment no longer includes Sanofi’s equity-accounted share of Regeneron’s profits for all the periods presented.

The Vaccines segment comprises, for all geographical territories, the commercial operations of Sanofi Pasteur, together with research, development and production activities dedicated to vaccines.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for Sanofi's Consumer Healthcare products, together with research, development and production activities dedicated to those products.

Inter-segment transactions are not material.

The costs of Sanofi’s global functions (External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.) are managed centrally at group-wide level, and are presented within the “Other” category. That category also includes other reconciling items such as retained commitments in respect of divested activities.

Following the Capital Markets Day held in February 2021, Sanofi changed the presentation of net sales for certain products within the General Medicines GBU and the Consumer Healthcare segment, and also reallocated certain expenses. In particular, IT costs relating to Sanofi's new digital organization – previously allocated to the Pharmaceutical, Vaccines, and Consumer Healthcare segments – are now included within the “Other” segment. The 2020 segment information presented hereinafter has been amended for comparative purposes in order to reflect those adjustments. Due to a lack of available data and the excessive complexity of the adjustments that would be required (especially to Sanofi's reporting tools), costs for 2019 have not been amended to reflect the changes arising from this new organization.

Information about operating segments for the years ended December 31, 2021, 2020 and 2019 is presented in Note D.35., “Segment information”.

B.27. Management of capital

In order to maintain or adjust the capital structure, Sanofi can adjust the amount of dividends paid to shareholders, repurchase its own shares, issue new shares, or issue securities giving access to its capital.

The following objectives are defined under the terms of Sanofi’s share repurchase programs:

- the implementation of any stock option plan giving entitlement to purchase shares in the Sanofi parent company;

- the allotment or sale of shares to employees under statutory profit sharing schemes and employee savings plans;
- the consideration-free allotment of shares (i.e. restricted share plans);
- the cancellation of some or all of the repurchased shares;
- market-making in the secondary market by an investment services provider under a liquidity contract in compliance with the ethical code recognized by the *Autorité des marchés financiers* (AMF);
- the delivery of shares on the exercise of rights attached to securities giving access to the capital by redemption, conversion, exchange, presentation of a warrant or any other means;
- the delivery of shares (in exchange, as payment, or otherwise) in connection with mergers and acquisitions;
- the execution by an investment services provider of purchases, sales or transfers by any means, in particular via off-market trading; or
- any other purpose that is or may in the future be authorized under the applicable laws and regulations.

Sanofi is not subject to any constraints on equity capital imposed by third parties.

Total equity includes ***Equity attributable to equity holders of Sanofi*** and ***Equity attributable to non-controlling interests***, as shown in the consolidated balance sheet.

Sanofi defines “Net debt” as (i) the sum of short-term debt, long-term debt and interest rate derivatives and currency derivatives used to hedge debt, minus (ii) the sum of cash and cash equivalents and interest rate derivatives and currency derivatives used to hedge cash and cash equivalents.

C/ Principal alliances

C.1. Alliance arrangements with Regeneron Pharmaceuticals, Inc. (Regeneron)

Collaboration agreements on human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed two agreements (amended in November 2009) relating to human therapeutic antibodies: (i) the Discovery and Preclinical Development Agreement, and (ii) the License and Collaboration Agreement, relating to clinical development and commercialization. Under the License and Collaboration Agreement, Sanofi had an option to develop and commercialize antibodies discovered by Regeneron under the Discovery and Preclinical Development Agreement.

Discovery and development

Because Sanofi decided not to exercise its option to extend the Discovery and Preclinical Development Agreement, that agreement expired on December 31, 2017.

As a result of Sanofi’s exercise of an option with respect to an antibody under the Discovery and Preclinical Development Agreement, such antibody became a "Licensed Product" under the License and Collaboration Agreement, pursuant to which Sanofi and Regeneron co-develop the antibody with Sanofi initially being wholly responsible for funding the development program. On receipt of the first positive Phase III trial results for any antibody being developed under the License and Collaboration Agreement, the subsequent development costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under the License and Collaboration Agreement are recognized by Sanofi as a reduction in the line item ***Research and development expenses***. Co-development with Regeneron of the antibodies Dupixent®, Kevzara® and REGN3500 (SAR440340 - itepekimab) is ongoing under the License and Collaboration Agreement as of December 31, 2021.

Once a product begins to be commercialized, and provided that the share of quarterly results under the agreement represents a profit, Sanofi is entitled to an additional portion of Regeneron’s profit-share (capped at 10% of Regeneron’s share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration (see footnote g(ii) to the table provided in Note D.21.1., “Off balance sheet commitments relating to operating activities”).

On the later of (i) 24 months before the scheduled launch date or (ii) the first positive Phase III trial results, Sanofi and Regeneron share the commercial expenses of the antibodies co-developed under the License and Collaboration Agreement.

Commercialization

Sanofi is the lead party with respect to the commercialization of all co-developed antibodies, and Regeneron has certain option rights to co-promote the antibodies. Regeneron has exercised its co-promotion rights in the United States and in certain other countries. Sanofi recognizes all sales of the antibodies. Profits and losses arising from commercial operations in the United States are split 50/50. Outside the United States, Sanofi is entitled to between 55% and 65% of profits depending on sales of the antibodies, and bears 55% of any losses. The share of profits and losses due to or from Regeneron under the agreement is recognized within the line items ***Other operating income*** or ***Other operating expenses***, which are components of ***Operating income***.

In addition, Regeneron is entitled to receive payments contingent on the attainment of specified levels of aggregate sales on all antibodies outside the United States, on a rolling twelve-month basis.

A liability for those payments is recognized in the balance sheet when it is probable that the specified level of aggregate sales will be met. The opposite entry for that liability is capitalized within ***Other intangible assets*** in the balance sheet. A payment was made in 2021 following the attainment of $1.5 billion of sales of all antibodies outside the United States on a rolling twelve-month basis.

Amendments to the collaboration agreements

In January 2018, Sanofi and Regeneron signed a set of amendments to their collaboration agreements, including an amendment that allowed for the funding of additional programs on Dupixent® and REGN3500 (SAR440340 – itepekimab) with an intended focus on extending the current range of indications, finding new indications, and improving co-morbidity between multiple pathologies.

Effective April 1, 2020, Sanofi and Regeneron signed a Cross License and Commercialization Agreement for Praluent®, whereby Sanofi obtained sole ex-US rights to Praluent®, and Regeneron obtained sole US rights to Praluent® along with a right to 5% royalties on Sanofi's sales of Praluent® outside the United States. Each party is solely responsible for the development, manufacturing and commercialization of Praluent® in their respective territories. Although each company has responsibility for supplying Praluent® in its respective territory, the companies have entered into agreements to support manufacturing needs for each other.

Effective September 30, 2021, Sanofi and Regeneron signed an amendment to their collaboration agreement in order to specify allocations of responsibilities and associated resources between the two parties in connection with the co-promotion of Dupixent® in certain countries. The terms of the collaboration relating to REGN3500 (SAR440340 – itepekimab) are unchanged.

Immuno-oncology (IO) collaboration agreements

On July 1, 2015, Sanofi and Regeneron signed two agreements – the IO Discovery and Development Agreement and the IO License and Collaboration Agreement (IO LCA) – relating to new antibody cancer treatments in the field of immuno-oncology.

The Amended IO Discovery Agreement, effective from December 31, 2018, was terminated through a Letter Amendment dated March 16, 2021 in which Sanofi formalized its opt-out from the BCMAxCD3 and MUC16xCD3 programs.

Libtayo® (cemiplimab)

Under the 2015 IO LCA as amended in January 2018, Sanofi and Regeneron committed funding of no more than $1,640 million, split on a 50/ 50 basis ($820 million per company), for the development of REGN2810 (cemiplimab, trademark Libtayo®), a PD-1 inhibitor antibody. The funding was raised to $1,840 million by way of amendment effective on September 30, 2021. Regeneron is responsible for the commercialization of Libtayo® in the United States, and Sanofi in all other territories. Sanofi has exercised its option to co-promote Libtayo® in the United States. In 2021, Regeneron exercised its option to co-promote Libtayo® in certain other countries.

The IO LCA also provided for a one-time milestone payment of $375 million by Sanofi to Regeneron in the event that sales of a PD-1 product were to exceed, in the aggregate, $2 billion in any consecutive 12-month period.

Under the IO LCA Sanofi and Regeneron share equally in profits and losses in connection with the commercialization of collaboration products, except that Sanofi is entitled to an additional portion of Regeneron's profit-share (capped at 10% of Regeneron's share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties under the IO Discovery Agreement, as amended.

In September 2018, the US Food and Drug Administration (FDA) approved Libtayo® (cemiplimab) for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. Libtayo® is the first and only product specifically approved and available in the United States for advanced stage CSCC. In July 2019, the European Medicines Agency (EMA) granted marketing authorization for Libtayo® for patients with metastatic or locally advanced CSCC who are not candidates for surgery.

In February 2021, the FDA approved Libtayo® for patients with locally advanced basal cell carcinoma (BCC), granted accelerated approval for patients with metastatic BCC, and approved Libtayo® for first-line monotherapy for patients with advanced non-small cell lung cancer (NSCLC) with PD-L1 expression of at least 50%. In June 2021, the EMA approved Libtayo® as a first-line treatment for patients with advanced NSCLC with PD-L1 expression of at least 50% and for advanced basal cell carcinoma. The extensive clinical program for Libtayo® is focused on difficult-to-treat cancers. In skin cancer, this includes trials in adjuvant and neoadjuvant CSCC. Libtayo® is also being investigated in pivotal trials in NSCLC (in combination with chemotherapy) and cervical cancer, as well as in combination with either conventional or novel therapeutic approaches for other solid tumors and blood cancers. These potential uses are investigational, and their safety and efficacy have not been evaluated by any regulatory authority.

Investor agreement

In January 2014, Sanofi and Regeneron amended the investor agreement entered into by the two companies in 2007. Under the terms of the amendment, Sanofi accepted various restrictions, including "standstill" provisions that contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron or acquiring more than 30% of Regeneron's capital stock (consisting of the outstanding shares of common stock and the shares of Class A stock). This prohibition remains in place until the earlier of (i) the later of the fifth anniversaries of the expiration or earlier termination of the Zaltrap® collaboration agreement with Regeneron (related to the development and commercialization of Zaltrap®) or the collaboration agreement with Regeneron on monoclonal antibodies (see "Collaboration agreements on human therapeutic antibodies" above), each as amended and (ii) other specified events.

Sanofi also agreed to vote as recommended by Regeneron's Board of Directors, except that it could elect to vote proportionally with the votes cast by all of Regeneron's other shareholders with respect to certain change-of-control transactions, and to vote in its sole discretion with respect to liquidation or dissolution, stock issuances equal to or exceeding 20% of the outstanding shares or voting rights of Regeneron's Class A Stock and Common Stock (taken together), and new equity compensation plans or amendments if not materially consistent with Regeneron's historical equity compensation practices. Sanofi began to account for its interest in Regeneron using the equity method in April 2014. Starting in 2018 Sanofi began to sell a small amount of shares of Regeneron stock pursuant to a Letter Agreement entered into with Regeneron.

On May 29, 2020, Sanofi announced the closing of its sale of 13 million shares of Regeneron common stock in a registered offering and a private sale to Regeneron (see Note D.2.).

At the same date an amendment to the Investor Agreement became effective, which stipulates inter alia that (i) the "standstill" provisions in the Investor Agreement, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron, will continue to apply; (ii) the voting commitments contained in the Investor Agreement will continue to apply to shares held by Sanofi; (iii) Sanofi will no longer have the right to designate an independent board member on the Regeneron Board of Directors.

Pursuant to subsequent sales, as of December 31, 2021 Sanofi held 279,766 shares of Regeneron stock.

C.2. Alliance arrangements with Bristol-Myers Squibb (BMS)

Two of Sanofi's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).

On September 27, 2012, Sanofi and BMS signed an agreement relating to their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets.

Under the terms of this agreement, effective January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico ("Territory B"), giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS received royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in Territory B) until 2018, and also received a payment of $200 million from Sanofi in December 2018, part of which is for buying out the non-controlling interests. Rights to Plavix® in Territory B remained unchanged and continued to be governed by the terms of the original agreement until February 28, 2020.

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the new agreement, Sanofi recognized in its consolidated financial statements the revenue and expenses generated by its own operations. Since January 2019 onwards, there has no longer been any share of profits reverting to BMS (previously presented within ***Net income attributable to non-controlling interests*** in the income statement).

In Territory B for Plavix®, which was managed by BMS, the Plavix® business was conducted through the Territory B partnerships, which were jointly owned by BMS and Sanofi. Sanofi recognized its share of profits and losses within the line item ***Share of profit/(loss) from investments accounted for using the equity method***.

On February 28, 2020, Sanofi purchased all BMS's interests (50.1%) in each of the Territory B partnerships for a cumulative purchase price of $12 million. Following a transition period, Sanofi has been commercializing Plavix® under its own label since July 1, 2020.

D/ Presentation of the financial statements

D.1. Principal changes in the scope of consolidation in 2021

Acquisition of Kymab

On April 8, 2021, Sanofi acquired the entire share capital of Kymab for an upfront payment of $1.1 billion (€973 million) and up to $350 million contingent upon reaching certain development milestones.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was accounted for as an asset acquisition given that the principal asset (the KY1005 project, currently in Phase II clinical development, and relating to the human monoclonal antibody OX40L, an essential regulator of the immune system) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €965 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €932 million.

Acquisition of Kiadis

On November 2, 2020, Sanofi and Kiadis, a biopharmaceutical company developing novel "off-the-shelf" natural killer (NK) cell therapies for patients with life-threatening diseases, entered into a definitive agreement whereby Sanofi was to make a public offer to acquire the entire share capital of Kiadis, i.e. 61 million shares, at a cash price of €5.45 per share.

The acquisition was approved unanimously by the Boards of Directors of Sanofi and Kiadis, and 95.03% of the share capital of Kiadis had been tendered into the offer as of April 16, 2021. As of the end of the post-closing acceptance period on April 29, 2021, Sanofi held 97.39% of the share capital of Kiadis, and launched a statutory public buy-out procedure in order to obtain 100% of the share capital.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was accounted for as an asset acquisition given that the principal asset (the K-NK technology platform) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €341 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €326 million.

Acquisition of Tidal

On April 9, 2021, Sanofi acquired Tidal Therapeutics, a privately owned, pre-clinical stage biotech company with a unique mRNA-based approach for in vivo reprogramming of immune cells. The new technology platform will expand Sanofi's research capabilities in immuno-oncology and inflammatory diseases, and may have applicability to other disease areas as well.

Tidal Therapeutics was acquired for an upfront payment of $160 million (€136 million), and up to $310 million contingent upon reaching certain development milestones.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was accounted for as an asset acquisition given that the principal asset (the unique mRNA-based in vivo reprogramming technology) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €130 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €135 million.

Acquisition of Translate Bio

On August 3, 2021, Sanofi entered into a definitive agreement with Translate Bio, a clinical-stage mRNA therapeutics company, under which Sanofi was to acquire all outstanding shares of Translate Bio for $38 per share. The Sanofi and Translate Bio Boards of Directors unanimously approved the transaction.

The acquisition of Translate Bio by Sanofi was completed on September 14, 2021, with Sanofi holding the entire share capital of Translate Bio upon expiration of the squeeze-out procedure.

The provisional purchase price allocation, as presented in the table below, led to the recognition of goodwill of €2,179 million:

(€ million)	Fair value at acquisition date
Other intangible assets	396
Deferred tax liabilities	(93)
Other current and non-current assets and liabilities	174
Cash and cash equivalents	247
Shire contingent consideration liability (see Note D.18.)	(323)
Net assets of Translate Bio	**401**
Goodwill	2,179
Purchase price	**2,580**

The other intangible assets mainly comprise a messenger RNA technological platform applied to the development of vaccines and therapeutic agents.

Goodwill mainly represents the effects of expected future synergies and other benefits to be derived from the integration of Translate Bio into the Sanofi group, in particular by accelerating the delivery of development programs.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

Translate Bio has no commercial operations, and has made a negative contribution of €72 million to Sanofi's consolidated net income since the acquisition date.

Acquisition-related costs recognized in profit or loss in 2021 were mainly recorded within the line item ***Other operating expenses***, and amounted to €13 million.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €2,333 million.

Under the terms of the collaboration agreement between Sanofi and Translate Bio as announced on June 23, 2020, Sanofi held an equity interest of approximately 5% in Translate Bio. As of the date when Sanofi obtained control of Translate Bio, that interest was remeasured at the purchase price of $38 per share. The change in fair value was recognized within ***Other comprehensive income***, in accordance with paragraph 42 of IFRS 3 (see Note D.7.).

Acquisition of Kadmon

On September 8, 2021, Sanofi entered into a definitive merger agreement with Kadmon, a biopharmaceutical company that discovers, develops and markets transformative therapies for disease areas with significant unmet medical needs. Shareholders of Kadmon common

stock received $9.50 per share in cash, representing a transaction valued at $1.9 billion on a fully-diluted basis. The Sanofi and Kadmon Boards of Directors unanimously approved the transaction.

The acquisition of Kadmon by Sanofi was completed on November 9, 2021, with Sanofi holding the entire share capital of Kadmon upon expiration of the squeeze-out procedure.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was therefore accounted for as an asset acquisition given that the principal asset (belumosudil, commercialized in the United States under the brand name Rezurock™) concentrates substantially all of the fair value of the acquired set of activities and assets.

Of the total acquisition price paid, €1,739 million was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows is a net cash outflow of €1,575 million.

Acquisition of Origimm

On December 3, 2021, Sanofi acquired the entire share capital of Origimm Biotechnology GmbH, a privately owned Austrian biotechnology company specializing in the discovery of virulent skin microbiome components and antigens from bacteria that cause skin diseases such as acne, for an upfront payment of €55 million and up to €95 million contingent upon reaching certain development and regulatory milestones.

Sanofi elected to apply the optional test to identify concentration of fair value under paragraph B7A of IFRS 3. The transaction was therefore accounted for as an asset acquisition given that the principal asset (the group of Propionibacterium acnes antigens) concentrates substantially all of the fair value of the acquired set of activities and assets.

Nearly €55 million of the acquisition price paid was allocated to ***Other intangible assets*** in accordance with IAS 38. The difference between that amount and the acquisition price corresponds to the other assets acquired and liabilities assumed as part of the transaction.

The impact of this acquisition as reflected within the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** in the consolidated statement of cash flows for the year ended December 31, 2021 is a net cash outflow of €50 million.

D.2. Principal changes in the scope of consolidation in 2020 and 2019

D.2.1. Principal changes in the scope of consolidation in 2020

Acquisition of Principia

On August 17, 2020, Sanofi and Principia Biopharma Inc. (“Principia”), a late-stage biopharmaceutical company focused on developing treatments for autoimmune diseases, entered into a definitive agreement under which Sanofi was to acquire all the outstanding shares of Principia for $100 per share. The transaction was approved unanimously by the Boards of Directors of Sanofi and Principia. Sanofi's acquisition of Principia was completed on September 28, 2020, with Sanofi holding the entire share capital of Principia upon expiration of the squeeze-out procedure. The final purchase price allocation, as presented in the table below, led to the recognition of goodwill of €912 million:

(€ million)	Fair value at acquisition date
Other intangible assets	2,534
Other current and non-current assets and liabilities	(38)
Cash and cash equivalents	186
Net deferred tax position	(436)
Net assets of Principia	**2,246**
Goodwill	912
Purchase price	**3,158**

The other intangible assets mainly comprise:

- rilzabrutinib (PRN 1008), a molecule undergoing clinical trials for various indications in immuno-inflammatory diseases and rare blood disorders; and
- tolebrutinib (PRN 2246/SAR442168), a molecule currently undergoing clinical trials for the treatment of multiple sclerosis and other diseases of the central nervous system.

Goodwill represents (i) the pipeline of future products in pre-clinical research and development; (ii) the capacity to draw on a specialized structure to refresh the existing product portfolio; and (iii) the competencies of Principia staff.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

No material adjustment was required on completion of the final purchase price allocation.

Acquisition of Synthorx

On December 9, 2019, Sanofi and Synthorx Inc. ("Synthorx"), a clinical-stage biotechnology company focused on prolonging and improving the lives of people suffering from cancer and autoimmune disorders, entered into a definitive agreement under which Sanofi was to acquire all of the outstanding shares of Synthorx for $68 per share. The transaction was unanimously approved by both the Sanofi and Synthorx Boards of Directors. On December 23, 2019, Sanofi launched a public tender offer to acquire all of the outstanding ordinary shares of Synthorx for $68 per share in cash, without interest and net of any applicable withholding taxes. The acquisition of Synthorx was completed on January 23, 2020, with Sanofi holding the entire share capital of Synthorx upon expiration of the squeeze-out procedure. The final purchase price allocation, as presented in the table below, led to the recognition of goodwill of €930 million:

(€ million)	Fair value at acquisition date
Other intangible assets	1,549
Other current and non-current assets and liabilities	36
Net deferred tax position	(269)
Net assets of Synthorx	**1,316**
Goodwill	930
Purchase price	**2,246**

The other intangible assets mainly comprise THOR-707, a molecule currently in Phase I clinical trials that stimulates T lymphocytes, and as such has potential as a cancer immunotherapy.

Goodwill represents (i) the pipeline of future products in pre-clinical research and development; (ii) the capacity to draw on a specialized structure to refresh the existing product portfolio; (iii) the competencies of Synthorx staff; (iv) benefits derived from the creation of new growth platforms; and (v) expected future synergies and other benefits from the combination of Synthorx and Sanofi.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

No material adjustment was required on completion of the final purchase price allocation.

Transaction related to the equity-accounted investment in Regeneron

From the beginning of April 2014, Sanofi accounted for its investment in Regeneron using the equity method. As from that date, in accordance with the Investor Agreement as amended in early 2014, Sanofi had the right to designate a member of the Regeneron Board of Directors.

On May 29, 2020, Sanofi closed the transaction announced on May 25, 2020 involving the sale of its equity investment in Regeneron (with the exception of 400,000 shares), through (i) a registered public offering in the United States and internationally and (ii) a share repurchase by Regeneron. Sanofi divested 13 million shares of Regeneron common stock (of which 10.6 million were sold by Sanofi) through the public offering at a price of $515 per share, raising a total amount of $6,703 million; and Regeneron repurchased 9.8 million of its own shares of common stock directly from Sanofi for $5,000 million, at the offer price less a subscription discount ($509.85 per share). The total sale proceeds (before transaction-related costs) amounted to €10,575 million. At the same time, Sanofi as a result of this transaction lost the right to designate a member of the Regeneron Board of Directors under the amended Investor Agreement. Finally, as of May 29, 2020 Sanofi retained ownership of 400,000 Regeneron shares in order to continue to partially fund its commitments to invest in the development programs for cemiplimab (REGN2810) and dupilumab, in line with the 2018 Letter Agreement under which Sanofi is permitted to sell up to 1.4 million shares through the end of 2020. As of December 31, 2021, Sanofi had sold 779,320 Regeneron shares under that agreement. The number of Regeneron shares retained by Sanofi is 279,766 as of December 31, 2021 (see Note C.1.).

Sanofi's equity investment in Regeneron was accounted for by the equity method until May 29, 2020. As of that date, the carrying amount of the investment was €3,668 million; that amount was reversed out on closing of the transaction. Before tax effects, the gain on the divestment amounted to €7,382 million, including (i) a gain of €318 million arising on the currency translation reserve associated with Regeneron, which was taken to profit or loss in accordance with IAS 21; (ii) the deduction of transaction-related costs of €64 million; and (iii) a gain of €157 million on the remeasurement of the 400,000 retained shares at their quoted market price as of May 29, 2020 ($612.81). In accordance with IFRS 9 (Financial Instruments), the retained shares were classified in the ***"Equity instruments at fair value through other comprehensive income"*** category on the transaction date, at a value of €221 million (see Note D.7.).

The tax charge arising on the transaction was €502 million.

Given the material impact of this transaction, and to facilitate users' understanding of the financial statements, the pre-tax gain on this transaction is presented as a separate line item in the consolidated income statement, ***Gain on Regeneron investment arising from the transaction of May 29, 2020***.

The net cash inflow from the transaction was €10,370 million, which (for the reason cited above) is presented as a separate line item in the consolidated statement of cash flows, ***Net proceeds from sale of Regeneron shares on May 29, 2020.***

Sale of Seprafilm®

On November 27, 2019, Sanofi entered into a definitive agreement to sell Seprafilm® to Baxter. The sale was completed on February 14, 2020. Sanofi recognized a pre-tax gain of €129 million.

The impact of this sale, reflected in the line item ***Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax*** within the consolidated statement of cash flows, was a net cash inflow before tax of €311 million.

D.2.2. Principal changes in the scope of consolidation in 2019

The impacts of the acquisitions carried out in 2019 were not material to the Sanofi consolidated financial statements, and Sanofi did not divest any material operations or companies during the year.

D.3. Property, plant and equipment

D.3.1. Property, plant and equipment owned

Property, plant and equipment owned by Sanofi is comprised of the following items:

(€ million)	Land	Buildings	Machinery and equipment	Fixtures, fittings and other	Property, plant and equipment in process	Total
Gross value at January 1, 2019	**283**	**6,883**	**10,468**	**2,579**	**2,484**	**22,697**
Acquisitions and other increases	—	10	50	56	1,145	1,261
Disposals and other decreases	(3)	(42)	(148)	(114)	(12)	(319)
Currency translation differences	6	80	64	17	33	200
Transfers[(a)]	(31)	351	619	49	(1,259)	(271)
Gross value at December 31, 2019	**255**	**7,282**	**11,053**	**2,587**	**2,391**	**23,568**
Changes in scope of consolidation	—	6	3	1	—	10
Acquisitions and other increases	—	16	40	46	1,208	1,310
Disposals and other decreases	(11)	(173)	(177)	(123)	(3)	(487)
Currency translation differences	(13)	(264)	(276)	(67)	(91)	(711)
Transfers[(a)]	5	(39)	484	80	(1,051)	(521)
Gross value at December 31, 2020	**236**	**6,828**	**11,127**	**2,524**	**2,454**	**23,169**
Changes in scope of consolidation	—	11	15	2	2	30
Acquisitions and other increases	—	10	51	39	1,404	1,504
Disposals and other decreases	(3)	(75)	(153)	(80)	(3)	(314)
Currency translation differences	6	169	155	34	79	443
Transfers[(a)]	1	227	453	136	(839)	(22)
Gross value at December 31, 2021	**240**	**7,170**	**11,648**	**2,655**	**3,097**	**24,810**
Accumulated depreciation & impairment at January 1, 2019	**(19)**	**(3,796)**	**(7,230)**	**(1,914)**	**(87)**	**(13,046)**
Depreciation expense	—	(357)	(586)	(194)	—	(1,137)
Impairment losses, net of reversals	(4)	(33)	(4)	(2)	(55)	(98)
Disposals and other decreases	2	54	140	106	11	313
Currency translation differences	—	(40)	(40)	(12)	—	(92)
Transfers[(a)]	10	107	60	32	—	209
Accumulated depreciation & impairment at December 31, 2019	**(11)**	**(4,065)**	**(7,660)**	**(1,984)**	**(131)**	**(13,851)**
Depreciation expense	—	(356)	(605)	(182)	—	(1,143)
Impairment losses, net of reversals	—	(24)	(12)	(7)	—	(43)
Disposals and other decreases	1	168	166	117	8	460
Currency translation differences	—	127	169	49	—	345
Transfers[(a)]	—	252	150	26	—	428
Accumulated depreciation & impairment at December 31, 2020	**(10)**	**(3,898)**	**(7,792)**	**(1,981)**	**(123)**	**(13,804)**
Depreciation expense	—	(306)	(592)	(167)	—	(1,065)
Impairment losses, net of reversals	—	(3)	(22)	(2)	(12)	(39)
Disposals and other decreases	—	74	149	75	1	299
Currency translation differences	—	(80)	(99)	(29)	—	(208)
Transfers[(a)]	1	23	16	(11)	6	35
Accumulated depreciation & impairment at December 31, 2021	**(9)**	**(4,190)**	**(8,340)**	**(2,115)**	**(128)**	**(14,782)**
Carrying amount at December 31, 2019	244	3,217	3,393	603	2,260	9,717
Carrying amount at December 31, 2020	226	2,930	3,335	543	2,331	9,365
Carrying amount at December 31, 2021	**231**	**2,980**	**3,308**	**540**	**2,969**	**10,028**

(a) This line mainly comprises property, plant and equipment in process brought into service during the period, but also includes the effect of the reclassification of assets to Assets held for sale or exchange, and for 2019 the reclassification of assets held under finance leases to Right-of-use assets on first-time application of IFRS 16.

The table below sets forth acquisitions and capitalized interest by operating segment for the years ended December 31, 2021, 2020 and 2019:

(€ million)	2021	2020	2019
Acquisitions	**1,504**	**1,310**	**1,261**
Pharmaceuticals	1,007	831	846
Industrial facilities	*534*	*634*	*682*
Research sites	*277*	*152*	*87*
Other	*199*	*45*	*77*
Vaccines	421	384	405
Consumer Healthcare	73	95	10
Capitalized interest	**14**	**11**	**14**

Off balance sheet commitments relating to property, plant and equipment as of December 31, 2021, 2020 and 2019 are set forth below:

(€ million)	2021	2020	2019
Firm orders of property, plant and equipment	769	708	398
Property, plant and equipment pledged as security for liabilities	9	—	107

The table below sets forth the net impairment losses recognized in each of the last three financial periods:

(€ million)	2021	2020	2019
Net impairment losses on property, plant and equipment	**39**	**43**	**98**

D.3.2. Property, plant and equipment leased – right-of-use assets

Right-of-use assets relating to property, plant and equipment leased by Sanofi are analyzed in the table below:

(€ million)	Right-of-use assets
Gross value at January 1, 2019	**1,439**
Acquisitions and other increases	157
Disposals and other decreases	(31)
Currency translation differences	18
Gross value at December 31, 2019	**1,583**
Changes in scope of consolidation	15
Acquisitions and other increases	340
Disposals and other decreases	(121)
Currency translation differences	(85)
Transfers[a]	(21)
Gross value at December 31, 2020	**1,711**
Changes in scope of consolidation	93
Acquisitions and other increases[b]	963
Disposals and other decreases	(91)
Currency translation differences	76
Transfers[a]	(7)
Gross value at December 31, 2021	**2,745**
Accumulated depreciation & impairment at January 1, 2019	**(8)**
Depreciation and amortization expense	(282)
Disposals and other decreases	7
Accumulated depreciation & impairment at December 31, 2019	**(283)**
Depreciation and amortization expense	(299)
Disposals and other decreases	44
Currency translation differences	22
Transfers[a]	3
Accumulated depreciation & impairment at December 31, 2020	**(513)**
Depreciation and amortization expense	(315)
Disposals and other decreases	40
Currency translation differences	(15)
Transfers[a]	6
Accumulated depreciation & impairment at December 31, 2021	**(797)**
Carrying amount at December 31, 2019	1,300
Carrying amount at December 31, 2020	1,198
Carrying amount at December 31, 2021	**1,948**

(a) This line also includes the effect of the reclassification of assets to "Assets held for sale or exchange".

(b) In December 2018, Sanofi signed two leases on real estate assets in the United States (at Cambridge, Massachusetts) for an initial lease term of 15 years. The first lease, relating to office space, began in April 2021; Sanofi recognized a right-of-use asset of €320 million, as well as the lease liability. The second lease, relating to laboratory facilities, began on July 1, 2021; Sanofi recognized a right-of-use asset of €424 million, as well as the lease liability.

Leased assets are mainly comprised of office and industrial premises (95%) and the vehicle fleet (5%) as of December 31, 2021.

Annual lease costs on short term leases and low value asset leases amounted to €25 million in the year ended December 31, 2021, €27 million in the year ended December 31, 2020, and €50 million in the year ended December 31, 2019. Variable lease payments, sub-leasing activities, and sale-and-leaseback transactions were immaterial.

Total cash outflows on leases (excluding annual lease costs on short term leases and low value asset leases) amounted to €302 million in the year ended December 31, 2021, €269 million in the year ended December 31, 2020, and €302 million in the year ended December 31, 2019.

A maturity analysis of the lease liability is disclosed in Note D.17.2.

Commitments related to short-term leases and low value asset leases, including future payments for lease contracts committed but not yet commenced, are disclosed in Note D.21.

D.4. Goodwill and other intangible assets

Movements in goodwill comprise:

(€ million)	Goodwill
Balance at January 1, 2019	**44,235**
Acquisitions during the period	—
Other movements during the period[(a)]	(244)
Currency translation differences	528
Balance at December 31, 2019	**44,519**
Acquisitions during the period	1,843
Other movements during the period[(a)]	(75)
Currency translation differences	(1,923)
Balance at December 31, 2020	**44,364**
Acquisitions during the period	2,179
Other movements during the period[(a)]	(89)
Currency translation differences	1,602
Balance at December 31, 2021	**48,056**

(a) This line includes the amount of goodwill allocated to divested operations in accordance with paragraph 86 of IAS 36.

Acquisition of Translate Bio (2021)

The provisional purchase price allocation for Translate Bio resulted in the recognition of intangible assets (other than goodwill) of €396 million as of the acquisition date (September 14, 2021), and of goodwill provisionally measured at €2,179 million as of the acquisition date (see Note D.1.).

Acquisition of Principia (2020)

The final purchase price allocation for Principia resulted in the recognition of intangible assets (other than goodwill) of €2,534 million as of the acquisition date (September 28, 2020), and of goodwill measured at €912 million as of the acquisition date (see Note D.2.1.).

Acquisition of Synthorx (2020)

The final purchase price allocation for Synthorx resulted in the recognition of intangible assets (other than goodwill) totaling €1,549 million as of the acquisition date (January 23, 2020), and of goodwill measured at €930 million as of the acquisition date (see Note D.2.1.).

Movements in other intangible assets comprise:

(€ million)	Acquired R&D	Products, trademarks and other rights	Software	Total other intangible assets
Gross Value at January 1, 2019[a]	**7,422**	**61,800**	**1,504**	**70,726**
Acquisitions and other increases[a]	272	19	155	446
Disposals and other decreases	(236)	(569)	(50)	(855)
Currency translation differences[a]	86	889	9	984
Transfers[b]	(1,814)	1,814	(5)	(5)
Gross value at December 31, 2019[a]	**5,730**	**63,953**	**1,613**	**71,296**
Changes in scope of consolidation[c]	3,951	132	—	4,083
Acquisitions and other increases[a]	654	58	106	818
Disposals and other decreases	(44)	(243)	(46)	(333)
Currency translation differences[a]	(593)	(2,926)	(38)	(3,557)
Transfers[b]	(98)	100	(2)	—
Gross value at December 31, 2020[a]	**9,600**	**61,074**	**1,633**	**72,307**
Changes in scope of consolidation[c]	1,805	1,821	—	3,626
Acquisitions and other increases	339	159	118	616
Disposals and other decreases	(313)	(173)	(16)	(502)
Currency translation differences	560	2,234	24	2,818
Transfers[b]	(784)	791	(7)	—
Gross value at December 31, 2021	**11,207**	**65,906**	**1,752**	**78,865**
Accumulated amortization & impairment at January 1, 2019[a]	**(2,678)**	**(45,228)**	**(971)**	**(48,877)**
Amortization expense[a]	—	(2,167)	(127)	(2,294)
Impairment losses, net of reversals[d]	(847)	(2,757)	(23)	(3,627)
Disposals and other decreases	158	488	51	697
Currency translation differences	(31)	(648)	(8)	(687)
Transfers[b]	2	(2)	1	1
Accumulated amortization & impairment at December 31, 2019[a]	**(3,396)**	**(50,314)**	**(1,077)**	**(54,787)**
Amortization expense[a]	—	(1,707)	(112)	(1,819)
Impairment losses, net of reversals[d]	(328)	(2)	—	(330)
Disposals and other decreases	44	232	45	321
Currency translation differences	158	2,460	31	2,649
Transfers[b]	14	(14)	—	—
Accumulated amortization & impairment at December 31, 2020[a]	**(3,508)**	**(49,345)**	**(1,113)**	**(53,966)**
Amortization expense	—	(1,621)	(119)	(1,740)
Impairment losses, net of reversals[d]	(150)	(42)	—	(192)
Disposals and other decreases	313	133	16	462
Currency translation differences	(132)	(1,869)	(21)	(2,022)
Accumulated amortization & impairment at December 31, 2021	**(3,477)**	**(52,744)**	**(1,237)**	**(57,458)**
Carrying amount at December 31, 2019	2,334	13,639	536	16,509
Carrying amount at December 31, 2020	6,092	11,729	520	18,341
Carrying amount at December 31, 2021	**7,730**	**13,162**	**515**	**21,407**

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.).

(b) The "Transfers" line mainly relates to acquired R&D that came into commercial use during the period and is being amortized from that date.

(c) The "Changes in scope of consolidation" line corresponds to the fair value of intangible assets recognized in connection with acquisitions made during the period (see Notes D.1. and D.2.1.).

(d) See Note D.5.

"Products, trademarks and other rights" mainly comprise:

- "marketed products", with a carrying amount of €11.7 billion as of December 31, 2021 (versus €11.4 billion as of December 31, 2020 and €13.3 billion as of December 31, 2019) and a weighted average amortization period of approximately 10 years;
- "technological platforms", with a carrying amount of €1.2 billion as of December 31, 2021 (versus €0.2 billion as of December 31, 2020 and €0.2 billion as of December 31, 2019) and a weighted average amortization period of approximately 18 years; and
- "trademarks", with a carrying amount of €0.1 billion as of December 31, 2021 (versus €0.1 billion as of December 31, 2020 and €0.1 billion as of December 31, 2019) and a weighted average amortization period of approximately 13 years.

The table below provides information about the principal "marketed products", which were recognized in connection with major acquisitions made by Sanofi and represented 92% of the carrying amount of that item as of December 31, 2021:

(€ million)	Gross value	Accumulated amortization & impairment	Carrying amount at December 31, 2021	Amortization period (years)[a]	Residual amortization period (years)[b]	Carrying amount at December 31, 2020	Carrying amount at December 31, 2019
Genzyme	10,177	(9,145)	1,032	10	3	1,485	2,095
Boehringer Ingelheim Consumer Healthcare	3,647	(1,434)	2,213	17	13	2,489	2,699
Aventis	33,687	(33,614)	73	9	8	110	219
Chattem	1,280	(687)	593	23	12	602	711
Protein Sciences	806	(274)	532	13	9	554	667
Ablynx	1,966	(472)	1,494	14	11	1,861	2,029
Bioverativ	6,841	(3,776)	3,065	13	10	3,240	3,788
Kadmon	1,771	(21)	1,750	12	12	—	—
Total: principal marketed products	**60,175**	**(49,423)**	**10,752**			**10,341**	**12,208**

(a) Weighted averages. The amortization periods for these products vary between 1 and 25 years.
(b) Weighted averages.

Acquisitions of other intangible assets (excluding software) during 2021 amounted to €498 million.

Transfers during 2021 include the Translate Bio mRNA technological platform, which was brought into service during the period.

During 2020, some of the acquired research and development came into commercial use, and started being amortized from the date of marketing approval; the main items involved were Sarclisa®, indicated for the treatment of relapsed refractory multiple myeloma, and the meningococcal vaccine MenQuadfi®.

During 2019, some of the acquired research and development came into commercial use, and started being amortized from the date of marketing approval; the item involved was the acquired thrombotic thrombocytopenic purpura (aTTP) treatment Cablivi®.

Amortization of other intangible assets is recognized in the income statement within the line item ***Amortization of intangible assets***, except for amortization of software and other rights of an industrial or operational nature which is recognized in the relevant classification of expense by function. An analysis of amortization of software is shown in the table below:

(€ million)	2021	2020 [a]	2019 [a]
Cost of sales	18	19	11
Research and development expenses	3	2	3
Selling and general expenses	98	87	107
Other operating expenses	—	4	6
Total	**119**	**112**	**127**

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.).

D.5. Impairment of intangible assets and property, plant and equipment

Goodwill

In accordance with IAS 36, goodwill is allocated to groups of cash generating units (CGUs) at a level corresponding to the Pharmaceuticals, Consumer Healthcare and Vaccines segments. When testing goodwill annually for impairment, the recoverable amount is determined for each segment on the basis of value in use, determined using discounted estimates of the future cash flows in accordance with the policies described in Note B.6.1.

The allocation of goodwill as of December 31, 2021 is shown below:

(€ million)	Pharmaceuticals	Consumer Healthcare	Vaccines	Total
Goodwill	**37,902**	**6,567**	**3,587**	**48,056**

The value in use of each segment was determined by applying an after-tax discount rate to estimated future after-tax cash flows.

A separate discount rate is used for each segment to reflect the specific economic conditions of that segment.

The rates used for impairment testing in 2021 were 7.25% for the Pharmaceuticals segment, 7.00% for the Consumer Healthcare segment and 7.25% for the Vaccines segment; an identical value in use for Sanofi as a whole would be obtained by applying a uniform 7.2% rate to all three segments.

The pre-tax discount rates applied to estimated pre-tax cash flows are calculated by iteration from the previously-determined value in use. Those pre-tax discount rates were 9.5% for the Pharmaceuticals segment, 9.1% for the Consumer Healthcare segment and 9.9% for the Vaccines segment, and equate to a uniform rate of 9.6% for Sanofi as a whole.

The assumptions used in testing goodwill for impairment are reviewed annually. Apart from the discount rate, the principal assumptions used in 2021 were as follows:

- the perpetual growth rates applied to future cash flows were zero for the Pharmaceuticals and Vaccines segments, and 1% for the Consumer Healthcare segment;
- Sanofi also applies assumptions on the probability of success of current research and development projects, and more generally on its ability to renew the product portfolio in the longer term.

Value in use (determined as described above) is compared with the carrying amount, and this comparison is then subjected to sensitivity analyses by reference to the principal parameters, including:

- changes in the discount rate;
- changes in the perpetual growth rate; and
- fluctuations in operating margin.

No impairment of goodwill would need to be recognized in the event of a reasonably possible change in the assumptions used in 2021.

A value in use calculation for each of the segments would not result in an impairment loss using:

- a discount rate up to 4.1 percentage points above the rates actually used; or
- a perpetual growth rate up to 15.3 percentage points below the rates actually used; or
- an operating margin up to 8.8 percentage points below the rates actually used.

No impairment losses were recognized against goodwill in the years ended December 31, 2021, 2020 or 2019.

Other intangible assets

When there is evidence that an asset may have become impaired, the asset's value in use is calculated by applying an after-tax discount rate to the estimated future after-tax cash flows from that asset. For the purposes of impairment testing, the tax cash flows relating to the asset are determined using a notional tax rate incorporating the notional tax benefit that would result from amortizing the asset if its value in use were regarded as its depreciable amount for tax purposes. Applying after-tax discount rates to after-tax cash flows gives the same values in use as would be obtained by applying pre-tax discount rates to pre-tax cash flows.

The after-tax discount rates used in 2021 for impairment testing of other intangible assets in the Pharmaceuticals, Consumer Healthcare and Vaccines segments were obtained by adjusting Sanofi's weighted average cost of capital to reflect specific country and business risks, giving after-tax discount rates in a range from 7.25% to 8.25%.

In most instances, there are no market data that would enable fair value less costs to sell to be determined other than by means of developing a similar estimate based on future cash flows. Consequently, recoverable amount is in substance equal to value in use. The estimates used to determine value in use are sensitive to assumptions specific to the nature of the asset and to Sanofi's activities. Apart from the discount rate, the principal assumptions used in 2021 were as follows:

- mid-term and long-term sales forecasts;
- perpetual growth or attrition rates, when applicable; and
- probability of success of current research and development projects.

The assumptions used in testing intangible assets for impairment are reviewed at least annually.

In 2021, 2020 and 2019, impairment testing of other intangible assets (excluding software) resulted in the recognition of net impairment losses as shown below:

(€ million)	2021	2020	2019
Impairment of other intangible assets (excluding software)	**192**	**330**	**3,604**
Marketed products	42	2	2,757
Pharmaceuticals[(a)]	*1*	*2*	*2,405*
Consumer Healthcare[(b)]	*41*	—	*352*
Research and development projects[(c)]	150	328	847

(a) Impairment losses recognized in the year ended December 31, 2019 include €2,236 million on products in the Eloctate® franchise and €163 million on the marketed product Lemtrada®.

(b) The impairment loss of €352 million recognized in the year ended December 31, 2019 related to Zantac®.

(c) For 2021, this line relates to the discontinuation of the development of sutimlimab in the treatment of Immune Thrombocytopenic Purpura (ITP), and to the termination of various research projects in Vaccines. For 2020, this line mainly comprises impairment losses taken against R&D programs within the Specialty Care GBU, and the discontinuation of certain R&D programs and collaboration agreements in Diabetes. For 2019, it relates mainly to (i) the allocation of the impairment loss recognized for the Eloctate® franchise to the BIVV001 project (see (a) above), and (ii) the termination of the development program for sotagliflozin (€275 million).

Property, plant and equipment

Impairment losses taken against property, plant and equipment are disclosed in Note D.3.

D.6. Investments accounted for using the equity method

Investments accounted for using the equity method comprise associates and joint ventures (see Note B.1.), and are set forth below.

(€ million)	% interest	2021	2020	2019
Regeneron Pharmaceuticals, Inc.[a]	—	—	—	3,342
Infraserv GmbH & Co. Höchst KG[b]	31.2	80	72	70
MSP Vaccine Company[c]	50.0	88	44	36
Entities and companies managed by Bristol-Myers Squibb[d]	100.0	—	—	37
Other investments	—	82	85	106
Total		**250**	**201**	**3,591**

(a) Following the transaction of May 29, 2020 as described in Note D.2.1. above, which resulted in the divestment of 22.8 million Regeneron shares, Sanofi no longer exercises significant influence over Regeneron. As of that date, Sanofi retained 0.4 million Regeneron shares, classified in the "Equity instruments at fair value through other comprehensive income" category (see Note D.7.1.). As of December 31, 2021, Sanofi held 279,766 Regeneron shares.

(b) Joint venture.

(c) Joint venture. MSP Vaccine Company owns 100% of MCM Vaccine B.V.

(d) On February 28, 2020, Sanofi acquired from Bristol-Myers Squibb the remaining 50.1% equity interest not yet held by Sanofi in the three partnerships that organize the commercialization of Plavix® in the United States and Puerto Rico, for a total consideration of $12 million. The acquisition was accounted for in accordance with IFRS 3 (Business Combinations).

The table below shows Sanofi's overall share of (i) profit or loss and (ii) other comprehensive income from investments accounted for using the equity method, showing the split between associates and joint ventures in accordance with IFRS 12 (the amounts for each individual associate or joint venture are not material):

	2021		2020		2019	
(€ million)	Joint ventures	Associates	Joint ventures	Associates	Joint ventures	Associates
Share of profit/(loss) from investments accounted for using the equity method	26	13	4	355 [a]	15	240
Share of other comprehensive income from investments accounted for using the equity method	(6)	—	8	(311)	(7)	90
Total	**20**	**13**	**12**	**44**	**8**	**330**

(a) Includes €343 million for Sanofi's share of the net income of Regeneron up to and including May 29, 2020 (see Note D.2.1.).

The financial statements include arm's length commercial transactions between Sanofi and some equity-accounted investments that are classified as related parties. The principal transactions and balances with related parties are summarized below:

(€ million)	2021	2020	2019
Sales	70	75	24
Royalties and other income[a]	66	97	270
Accounts receivable and other receivables	116	50	151
Purchases and other expenses (including research expenses)[a]	178	747	1,334
Accounts payable and other payables	28	15	342

(a) For 2020, these amounts include transactions between Sanofi and Regeneron for the period from January 1 through May 29, 2020. The table above does not include the repurchase by Regeneron of its own shares from Sanofi (see Note D.2.1.).

There were no funding commitments to associates and joint ventures as of December 31, 2021 and in December 31, 2020, compared with €67 million as of December 31, 2019.

For off balance sheet commitments of an operational nature involving joint ventures, see Note D.21.1.

Regeneron

As mentioned in Note D.2.1., as a result of the sale of 22.8 million shares of Regeneron common stock on May 29, 2020, Sanofi ceased to exercise significant influence over Regeneron, and this investment is no longer accounted for using the equity method.

Key items from the 2019 consolidated financial statements of Regeneron, after adjustments to comply with IFRS (including those required to align on elective accounting treatments adopted by Sanofi) but before fair value remeasurements, are set forth below:

(€ million)	2019
Net sales and other revenues	7,023
Net income	1,882
Other comprehensive income for the period, net of taxes	113
Comprehensive income	1,995

(€ million)	December 31, 2019
Current assets	6,858
Non-current assets	6,627
Total assets	**13,485**
Current liabilities	1,870
Non-current liabilities	925
Total liabilities	**2,795**
Consolidated shareholders' equity of Regeneron	**10,690**

The table below shows a reconciliation to the carrying amount of the investment:

(€ million)	December 31, 2019
% interest	21%
Share of equity attributable to Sanofi	2,263
Goodwill	839
Fair value remeasurements of assets and liabilities at the acquisition date	811
Other items[(a)]	(571)
Carrying amount of the investment in Regeneron	3,342

(a) Mainly comprises the difference arising from Sanofi's share of the accumulated profits and losses and other changes in the net assets of Regeneron for the periods prior to first-time application of the equity method, and thereafter (i) Sanofi's share of the stock option expense recognized against equity in the books of Regeneron, and of the deferred taxes recognized against equity in respect of that expense in accordance with IAS 12 paragraph 68.C. and (ii) the effects of the elimination of internal profits between Sanofi and Regeneron.

The market value of Sanofi's investment in Regeneron as of December 31, 2019, based on the quoted stock market price per share in US dollars, is shown below:

	2019
Quoted stock market price per share ($)	375.48
Market value of investment in Regeneron ($ million)	8,767
Market value of investment in Regeneron (€ million)	7,820

D.7. Other non-current assets

Other non-current assets comprise:

(€ million)	2021	2020	2019
Equity instruments at fair value through other comprehensive income (D.7.1.)	823	588	380
Debt instruments at fair value through other comprehensive income (D.7.2.)	447	426	403
Other financial assets at fair value through profit or loss (D.7.3.)	902	890	892
Pre-funded pension obligations (Note D.19.1.)	408	177	155
Long-term prepaid expenses	59	92	115
Long-term loans and advances and other non-current receivables	485	537	521
Derivative financial instruments (Note D.20.)	3	24	37
Total	**3,127**	**2,734**	**2,503**

D.7.1. Equity instruments at fair value through other comprehensive income

Quoted equity investments

The line "Equity instruments at fair value through other comprehensive income" includes equity investments quoted in an active market with a carrying amount of €396 million as of December 31, 2021, €439 million as of December 31, 2020 and €114 million as of December 31, 2019.

The main change in the quoted equity investments included in the "Equity instruments at fair value through other comprehensive income" category during the year ended December 31, 2021 is described below:

- following finalization of the acquisition of Translate Bio on September 14, 2021 (see Note D.1.), the equity interest of approximately 5% in Translate Bio previously held by Sanofi is no longer accounted for as an equity instrument at fair value through other comprehensive income.

The main changes in the quoted equity investments included in the "Equity instruments at fair value through other comprehensive income" category during the year ended December 31, 2020 are described below:

- as mentioned in Note D.2.1., following the sale of 22.8 million shares of Regeneron common stock on May 29, 2020, Sanofi ceased to exercise significant influence over Regeneron, and this investment is no longer accounted for using the equity method (see Note D.6.). In accordance with IFRS 9 (Financial Instruments), the 400,000 shares retained by Sanofi were classified in the **"Equity instruments at fair value through other comprehensive income"** category as of May 29, 2020, at a carrying amount of €221 million. As of December 31, 2020, Sanofi held 279,766 Regeneron shares with a carrying amount of €111 million;
- an equity injection was made into Translate Bio under the terms of the collaboration and license agreement announced on June 23, 2020, with a carrying amount of €74 million as of December 31, 2020 and representing an equity interest of approximately 8% of Translate Bio as of that date;
- Sanofi owns equity interests in quoted biotechnology companies. Movements in the quoted market prices of the shares held in those companies generated a net gain of €357 million, recognized in "**Equity instruments at fair value through other comprehensive income"**.

The main changes in the quoted equity investments included in the "Equity instruments at fair value through other comprehensive income" category during the year ended December 31, 2019 are described below:

- on May 2, 2019, further to the announcement on April 8, 2019 of amendments to the terms of the agreement governing Sanofi's equity interest in Alnylam, Sanofi divested its entire holding of 10.6 million Alnylam shares, representing approximately 10% of Alnylam's equity capital. Proceeds from the divestment amounted to €706 million, net of taxes. The loss on the divestment was recognized in full in ***Other comprehensive income***;
- the entire equity interest held by Sanofi in MyoKardia, Inc. was divested during the first half of 2019. Proceeds from the divestment amounted to €118 million, net of taxes. The gain arising on the divestment was recognized in full in ***Other comprehensive income***;
- following the restructuring of Onduo LLC, finalized November 11, 2019, Sanofi received from Onduo a dividend in the form of DexCom shares valued at $122 million.

A 10% decline in stock prices of the quoted equity investments included within "Equity instruments at fair value through other comprehensive income" would have had a pre-tax impact of €(40) million on ***Other comprehensive income*** as of December 31, 2021.

Unquoted equity investments

The line item "Equity instruments at fair value through other comprehensive income" also includes equity investments not quoted in an active market with a carrying amount of €427 million as of December 31, 2021, €149 million as of December 31, 2020 and €266 million as of December 31, 2019.

The main change in the unquoted equity investments included in the "Equity instruments at fair value through other comprehensive income" category during the year ended December 31, 2021 is described below:

- on November 18, 2021, Sanofi announced an investment of $180 million (representing an equity interest of 14%) in the French start-up Okwin, under the terms of the strategic agreement signed by the two companies.

D.7.2. Debt instruments at fair value through other comprehensive income

The "Debt instruments at fair value through other comprehensive income" category includes quoted euro-denominated senior bonds amounting to €447 million as of December 31, 2021, including €152 million of securities obtained in exchange for financial assets held to meet obligations to employees under post-employment benefit plans.

Sanofi held €426 million of quoted senior bonds as of December 31, 2020 and €403 million as of December 31, 2019.

As regards debt instruments held to meet obligations to employees under post-employment benefit plans, an increase of 10 basis points in market interest rates as of December 31, 2021 would have had a pre-tax impact of €2 million on ***Other comprehensive income***.

As regards other quoted debt instruments, an increase of 10 basis points in market interest rates as of December 31, 2021 would have had a pre-tax impact of €1 million on ***Other comprehensive income***.

Other comprehensive income recognized in respect of "Equity instruments at fair value through other comprehensive income" and "Debt instruments at fair value through other comprehensive income" represented unrealized after-tax gains of €322 million for the year ended December 31, 2021, versus unrealized after-tax gains of €200 million for the year ended December 31, 2020 and unrealized after-tax losses of €80 million for the year ended December 31, 2019.

An analysis of the change in gains and losses recognized in ***Other comprehensive income***, and of items reclassified to profit or loss, is presented in Note D.15.7.

D.7.3. Other financial assets at fair value through profit or loss

The "Other financial assets at fair value through profit or loss" category includes:

- contingent consideration receivable by Sanofi following the dissolution of the Sanofi Pasteur MSD (SPMSD) joint venture, based on a percentage of MSD's future sales during the 2017-2024 period of specified products previously distributed by SPMSD (see Note D.12.).

  The fair value of the MSD contingent consideration was determined by applying the royalty percentage stipulated in the contract to discounted sales projections. A reduction of one percentage point in the discount rate would increase the fair value of the MSD contingent consideration by approximately 2%.

  Changes in the fair value of this contingent consideration are recognized in the income statement within the line item ***Fair value remeasurement of contingent consideration*** (see Note B.18.). As of December 31, 2021, the contingent consideration asset

amounted to €378 million (including a non-current portion of €275 million), versus €483 million (non-current portion: €374 million) as of December 31, 2020 and €492 million as of December 31, 2019;

- a portfolio of financial investments (amounting to €549 million as of December 31, 2021) held to fund a deferred compensation plan provided to certain employees (versus €453 million as of December 31, 2020 and €442 million as of December 31, 2019);
- unquoted securities not meeting the definition of equity instruments amounting to €78 million as of December 31, 2021 (versus €63 million as of December 31, 2020 and €52 million as of December 31, 2019).

D.8. Assets held for sale or exchange and liabilities related to assets held for sale or exchange

Assets held for sale or exchange, and liabilities related to assets held for sale or exchange, comprise:

(€ million)	December 31, 2021	December 31, 2020	December 31, 2019
Assets held for sale or exchange	**89**	**83**	**325**
Liabilities related to assets held for sale or exchange	**—**	**32**	**6**

As of December 31, 2021, assets held for sale mainly related to the divestment of a listed equity investment in the United States that remains subject to customary closing conditions, including regulatory clearances.

As of December 31, 2020, assets held for sale mainly related to the planned divestment of an industrial facility in North America.

As of December 31, 2019, assets held for sale mainly comprised assets associated with the sale of Seprafilm®, which was completed in the first half of 2020.

D.9. Inventories

Inventories comprise the following:

	2021			2020			2019		
(€ million)	Gross value	Allowances	Carrying amount	Gross value	Allowances	Carrying amount	Gross value	Allowances	Carrying amount
Raw materials	1,344	(66)	1,278	1,051	(76)	975	1,163	(76)	1,087
Work in process	5,579	(554)	5,025	5,398	(542)	4,856	5,104	(582)	4,522
Finished goods	2,696	(284)	2,412	2,739	(218)	2,521	2,629	(244)	2,385
Total	**9,619**	**(904)**	**8,715**	**9,188**	**(836)**	**8,352**	**8,896**	**(902)**	**7,994**

Allowances include write-downs of products on hand pending marketing approval, except in specific circumstances where it is possible to estimate that recovery of the value of inventories as of the end of the reporting period is highly probable.

Inventories pledged as security for liabilities amounted to €20 million as of December 31, 2021 (versus €17 million as of December 31, 2020 and €15 million as of December 31, 2019).

D.10. Accounts receivable

Accounts receivable break down as follows:

(€ million)	December 31, 2021	December 31, 2020	December 31, 2019
Gross value	7,705	7,633	8,090
Allowances	(137)	(142)	(153)
Carrying amount	**7,568**	**7,491**	**7,937**

The impact of allowances against accounts receivable in 2021 was a net expense of €12 million (versus a net expense of €30 million in 2020 and a net gain of €5 million in 2019).

The gross value of overdue receivables was €455 million as of December 31, 2021, compared with €549 million as of December 31, 2020 and €642 million as of December 31, 2019.

(€ million)	Overdue accounts gross value	Overdue by <1 month	Overdue by 1 to 3 months	Overdue by 3 to 6 months	Overdue by 6 to 12 months	Overdue by > 12 months
December 31, 2021	**455**	**169**	**151**	**67**	**12**	**56**
December 31, 2020	549	271	97	52	34	95
December 31, 2019	642	269	171	61	36	105

Amounts overdue by more than one month relate mainly to public-sector customers.

Some Sanofi subsidiaries have assigned receivables to factoring companies or banks without recourse. The amount of receivables derecognized was €3 million as of December 31, 2021 (€18 million as of December 31, 2020 and €214 million as of December 31, 2019). The residual guarantees relating to such transfers were immaterial as of December 31, 2021.

D.11. Other current assets

An analysis of ***Other current assets*** is set forth below:

(€ million)	2021	2020	2019
Tax receivables, other than corporate income taxes	802	687	603
Prepaid expenses	615	525	493
Other receivables[(a)]	805	567	735
Interest rate derivatives measured at fair value (see Note D.20.)	11	—	4
Currency derivatives measured at fair value (see Note D.20.)	284	58	184
Other current financial assets[(b)]	1,054	900	426
Total	**3,571**	**2,737**	**2,445**

(a) This line mainly comprises advance payments to suppliers.

(b) This line includes debt instruments derived from the 2021 acquisitions of Translate Bio and Kadmon, which had a maturity of more than three months at inception and of less than 12 months as of December 31, 2021; it also includes bank loans and receivables falling due within less than one year with high-grade counterparties. For 2019, this line includes an amount of $315 million deposited by Sanofi in an escrow account and released in March 2020 following the signature of an agreement to settle the CVR litigation with the trustee.

D.12. Financial assets and liabilities measured at fair value

Under IFRS 7 (Financial Instruments: Disclosures), fair value measurements must be classified using a fair value hierarchy with the following levels:

- level 1: quoted prices in active markets for identical assets or liabilities (without modification or repackaging);
- level 2: quoted prices in active markets for similar assets and liabilities, or valuation techniques in which all important inputs are derived from observable market data;
- level 3: valuation techniques in which not all important inputs are derived from observable market data.

The valuation techniques used are described in Note B.8.5.

The table below shows the balance sheet amounts of assets and liabilities measured at fair value.

		2021			2020			2019		
		Level in the fair value hierarchy			Level in the fair value hierarchy			Level in the fair value hierarchy		
(€ million)	Note	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Financial assets measured at fair value										
Quoted equity investments	D.7.1.	396	—	—	439	—	—	114	—	—
Unquoted equity investments	D.7.1.	—	—	427	—	—	149	—	—	290
Quoted debt securities	D.7.2.	447	—	—	426	—	—	403	—	—
Unquoted debt securities not meeting the definition of equity instruments	D.7.3.	—	—	78	—	—	63	—	—	52
Contingent consideration relating to divestments	D.7.3.	—	—	378	—	—	483	—	—	492
Financial assets held to meet obligations under deferred compensation plans	D.7.3. and D.11.	549	—	—	454	—	—	442	—	—
Non-current derivatives	D.7.	—	3	—	—	24	—	—	37	—
Current derivatives	D.11.	—	295	—	—	58	—	—	188	—
Mutual fund investments	D.13.	5,057	—	—	8,703	—	—	5,304	—	—
Total financial assets measured at fair value		**6,449**	**298**	**883**	**10,022**	**82**	**695**	**6,263**	**225**	**834**
Financial liabilities measured at fair value										
Bayer contingent purchase consideration arising from the acquisition of Genzyme	D.18.	—	—	59	—	—	104	—	—	156
MSD contingent consideration (European vaccines business)	D.18.	—	—	269	—	—	312	—	—	385
Shire contingent consideration arising from the acquisition of Translate Bio	D.18.	—	—	354	—	—	—	—	—	—
Other contingent consideration arising from business combinations and acquisitions	D.18.	—	—	32	—	—	189	—	—	259
Non-current derivatives	D.19.	—	6	—	—	92	—	—	10	—
Current derivatives	D.19.5	—	79	—	—	205	—	—	89	—
Total financial liabilities measured at fair value		**—**	**85**	**714**	**—**	**297**	**605**	**—**	**99**	**800**

No transfers between the different levels of the fair value hierarchy occurred during 2021.

D.13. Cash and cash equivalents

(€ million)	2021	2020	2019
Cash	1,358	1,144	701
Cash equivalents[(a)]	8,740	12,771	8,726
Cash and cash equivalents	**10,098**	**13,915**	**9,427**

(a) As of December 31, 2021, cash equivalents mainly comprised the following: (i) €5,057 million invested in euro and US dollar denominated money-market mutual funds (December 31, 2020: €8,703 million; December 31, 2019: €5,304 million); (ii) €2,768 million of term deposits (December 31, 2020: €3,259 million; December 31, 2019: €2,211 million) and (iii) €179 million in commercial paper (December 31, 2020: €74 million; December 31, 2019: €446 million). Cash equivalents also include €427 million held by captive insurance and reinsurance companies in accordance with insurance regulations (December 31, 2020: €425 million; December 31, 2019: €456 million).

D.14. Net deferred tax position

An analysis of the net deferred tax position is set forth below:

(€ million)	2021	2020 [(d)]	2019 [(d)]
Deferred taxes on:			
Consolidation adjustments (intragroup margin in inventory)	1,292	1,142	1,270
Provision for pensions and other employee benefits	1,117	1,156	1,268
Remeasurement of other acquired intangible assets	(3,079) [(a)]	(3,083)	(2,656)
Recognition of acquired property, plant and equipment at fair value	(26)	(27)	(33)
Equity interests in subsidiaries and investments in other entities[(b)]	(590)	(522)	(421)
Tax losses available for carry-forward	1,516	1,327	1,323
Stock options and other share-based payments	88	89	143
Accrued expenses and provisions deductible at the time of payment[(c)]	1,585	1,399	1,405
Other	1,078	925	798
Net deferred tax asset/(liability)	**2,981**	**2,406**	**3,097**

(a) As of December 31, 2021, includes remeasurements of the acquired intangible assets of Bioverativ (€977 million), Principia (€588 million), Genzyme (€261 million), and Synthorx (€335 million).

(b) In some countries, Sanofi is liable for withholding taxes and other tax charges when dividends are distributed. Consequently, Sanofi recognizes a deferred tax liability on the reserves of French and foreign subsidiaries (approximately €52.9 billion) which it regards as likely to be distributed in the foreseeable future. In determining the amount of the deferred tax liability as of December 31, 2021, Sanofi took into account changes in the ownership structure of certain subsidiaries, and the effects of changes in the taxation of dividends in France, following the ruling of the Court of Justice of the European Union in the Steria case and the resulting amendments to the 2015 Finance Act.

(c) Includes deferred tax assets related to restructuring provisions, amounting to €226 million as of December 31, 2021, €307 million as of December 31, 2020, and €259 million as of December 31, 2019.

(d) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

The reserves of Sanofi subsidiaries that would be taxable if distributed but for which no distribution is planned, and for which no deferred tax liability has therefore been recognized, totaled €10 billion as of December 31, 2021, compared with €11.5 billion as of December 31, 2020 and €10.9 billion as of December 31, 2019.

Most of Sanofi's tax loss carry-forwards are available indefinitely. For a description of policies on the recognition of deferred tax assets, refer to Note B.22. For each tax consolidation, the recognition of deferred tax assets is determined on the basis of profit forecasts that are consistent with Sanofi's medium-term strategic plan, and taking into consideration the tax consequences of the strategic opportunities available to Sanofi within the period of availability of tax loss carry-forwards and the specific circumstances of each tax consolidation. Deferred tax assets relating to tax loss carry-forwards as of December 31, 2021 amounted to €2,391 million, of which €875 million were not recognized (including €459 million in respect of capital losses). This compares with €1,658 million as of December 31, 2020 (of which €331 million were not recognized) and €1,640 million as of December 31, 2019 (of which €317 million were not recognized).

The table below shows when tax losses available for carry-forward are due to expire:

(€ million)	Tax losses available for carry-forward[(a)]
2022	43
2023	8
2024	18
2025	56
2026	85
2027 and later	7,434
Total as of December 31, 2021	**7,644**
Total as of December 31, 2020	**6,515**
Total as of December 31, 2019	**6,401**

(a) Excluding tax loss carry-forwards on asset disposals. Such carry-forwards amounted to €5 million as of December 31, 2021, €6 million as of December 31, 2020 and €1 million as of December 31, 2019.

Use of tax loss carry-forwards is limited to the entity in which they arose. In jurisdictions where tax consolidations are in place, tax losses can be netted against taxable income generated by entities in the same tax consolidation.

Deferred tax assets not recognized (primarily because their future recovery was not regarded as probable given the expected results of the entities in question) amounted to €615 million in 2021, €346 million in 2020 and €340 million in 2019.

D.15. Consolidated shareholders' equity

D.15.1. Share capital

As of December 31, 2021, the share capital was €2,527,121,390, consisting of 1,263,560,695 shares with a par value of €2. Treasury shares held by Sanofi are as follows:

	Number of shares (million)	% of share capital for the period
December 31, 2021	**11.02**	**0.872%**
December 31, 2020	8.28	0.658%
December 31, 2019	0.02	0.002%
January 1, 2019	1.94	0.156%

Treasury shares are deducted from shareholders' equity. Gains and losses on disposals of treasury shares are recorded directly in equity and are not recognized in net income for the period.

Movements in the share capital of the Sanofi parent company over the last three years are set forth below:

Date	Transaction	Number of shares
December 31, 2018		**1,247,395,472**
During 2019	Capital increase by exercise of stock subscription options[(a)]	2,745,853
During 2019	Capital increase by issuance of restricted shares[(b)]	3,704,786
December 31, 2019		**1,253,846,111**
During 2020	Capital increase by exercise of stock subscription options[(a)]	868,655
During 2020	Capital increase by issuance of restricted shares[(b)]	1,666,256
Board meeting of July 28, 2020	Capital increase reserved for employees	2,590,716
December 31, 2020		**1,258,971,738**
During 2021	Capital increase by exercise of stock subscription options[(a)]	190,076
During 2021	Capital increase by issuance of restricted shares[(b)]	1,836,179
Board meeting of July 28, 2021	Capital increase reserved for employees	2,562,702
December 31, 2021		**1,263,560,695**

(a) Shares issued on exercise of Sanofi stock subscription options.
(b) Shares vesting under restricted share plans and issued in the period.

For the disclosures about the management of capital required under IFRS 7, refer to Note B.27.

D.15.2. Restricted share plans

Restricted share plans are accounted for in accordance with the policies described in Note B.24.3. The principal characteristics of those plans are as follows:

	2021		2020		2019
Type of plan	**Performance share plan**	**Performance share plan**	**Performance share plan**	**Performance share plan**	**Performance share plan**
Date of Board meeting approving the plan	April 30, 2021	October 27, 2021	April 28, 2020	October 28, 2020	April 30, 2019
Service period	3 years	3 years	3 years	3 years	3 years
Total number of shares awarded	3,484,420	13,521	3,340,501	73,027	3,797,582
Of which with no market condition	2,209,901	—	2,536,893	—	3,797,582
Fair value per share awarded (€)[(a)]	77.27	—	82.36	—	67.90
Of which with market condition	1,274,519	13,521	803,608	73,027	—
Fair value per share awarded (€)[(b)]	71.30	68.45	76.11	63.18	—
Fair value of plan at the date of grant (€ million)	**262**	**1**	**270**	**5**	**258**

(a) Market price of Sanofi shares at the date of grant, adjusted for dividends expected during the vesting period.
(b) Weighting between (i) fair value determined using the Monte Carlo model and (ii) market price of Sanofi shares at the date of grant, adjusted for dividends expected during the vesting period.

The total expense recognized for all restricted share plans, and the number of restricted shares not yet fully vested, are shown in the table below:

	2021	2020	2019
Total expense for restricted share plans (€ million)	193	222	247
Number of shares not yet fully vested	9,507,849	10,546,612	10,908,503
Under 2021 plans	*3,364,895*	—	—
Under 2020 plans	*3,014,496*	*3,284,558*	—
Under 2019 plans	*3,128,458*	*3,375,717*	*3,662,806*
Under 2018 plans		*3,886,337*	*4,117,795*
Under 2017 plans		—	*3,127,902*

D.15.3. Capital increases

The characteristics of the employee share ownership plans awarded in the form of a capital increase reserved for employees in 2021 and 2020 are summarized in the table below; there were no capital increases reserved for employees in 2019.

	2021	2020
Date of Board meeting approving the plan	February 4, 2021	February 5, 2020
Subscription price (€)[(a)]	69.38	70.67
Subscription period	June 7-25, 2021	June 8-26, 2020
Number of shares subscribed	2,438,590	2,467,101
Number of shares issued immediately as employer's contribution	124,112	123,615

(a) Subscription price representing 80% of the average of the opening quoted market prices of Sanofi shares during the 20 trading days preceding June 3, 2021 and June 2, 2020, respectively.

The table below sets forth the expense recognized for each plan:

(€ million)	2021	2020
Expense recognized	51	52
of which employer's contribution	*11*	*11*

D.15.4. Repurchase of Sanofi shares

The Annual General Meetings of Sanofi shareholders held on April 30, 2021, April 28, 2020, April 30, 2019 and May 2, 2018 each authorized a share repurchase program for a period of 18 months. The following repurchases have been made under those programs:

(in number of shares and € million)	2021		2020		2019	
Year of authorization	Number of shares	Value	Number of shares	Value	Number of shares	Value
2021 program	2,765,388	242	—	—	—	—
2020 program	1,758,569	140	5,685,426	461	—	—
2019 program	—	—	3,982,939	361	—	—
2018 program	—	—	—	—	147,793	12

D.15.5. Reductions in share capital

There were no reductions in share capital during 2019, 2020 or 2021.

D.15.6. Currency translation differences

Currency translation differences comprise the following:

(€ million)	2021	2020 [a]	2019 [a]
Attributable to equity holders of Sanofi	(865)	(3,384)	632
Attributable to non-controlling interests	(42)	(55)	(36)
Total	**(907)**	**(3,439)**	**596**

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.).

The balance as of December 31, 2021 includes an after-tax amount of €(317) million relating to hedges of net investments in foreign operations (refer to Note B.8.3. for a description of the relevant accounting policy), versus €(136) million as of December 31, 2020 and €(260) million as of December 31, 2019.

The movement in ***Currency translation differences*** is mainly attributable to the US dollar.

D.15.7. Other comprehensive income

Movements within other comprehensive income are shown below:

(€ million)	2021	2020 [a]	2019 [a]
Actuarial gains/(losses):			
• Actuarial gains/(losses) excluding investments accounted for using the equity method (see Note D.19.1.)	685	(266)	(331)
• Actuarial gains/(losses) of investments accounted for using the equity method, net of taxes	1	(1)	(5)
• Tax effects	(36)	45	149
Equity instruments included in financial assets and financial liabilities:			
• Change in fair value (excluding investments accounted for using the equity method)	154	358	30
• Change in fair value (investments accounted for using the equity method, net of taxes)	—	(14)	80
• Equity risk hedging instruments designated as fair value hedges	11	(24)	(4)
• Tax effects	(18)	(84)	(48)
Items not subsequently reclassifiable to profit or loss	**797**	**14**	**(129)**
Debt instruments included in financial assets:			
• Change in fair value (excluding investments accounted for using the equity method)[b]	(21)	15	28
• Change in fair value (investments accounted for using the equity method, net of taxes)	—	—	—
• Tax effects	5	(3)	(5)
Cash flow and fair value hedges:			
• Change in fair value (excluding investments accounted for using the equity method)[c]	(6)	4	(13)
• Change in fair value (investments accounted for using the equity method, net of taxes)	—	—	—
• Tax effects	2	(2)	4
Change in currency translation differences:			
• Currency translation differences on foreign subsidiaries (excluding investments accounted for using the equity method)[b]	2,719	(3,870)	850
• Currency translation differences (investments accounted for using the equity method)[c]	(6)	32	64
• Currency translation differences related to the investment in Regeneron and reclassified to profit or loss[d]	—	(318)	—
• Hedges of net investments in foreign operations[c]	(254)	180	(163)
• Tax effects[d]	71	(59)	48
Items subsequently reclassifiable to profit or loss	**2,510**	**(4,021)**	**813**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

(b) Amounts reclassified to profit or loss: €4 million in 2021, €5 million in 2020, and immaterial in 2019.

(c) Amounts reclassified to profit or loss: €12 million in 2021, €1 million in 2020 and €27 million in 2019.

(d) Relates to the translation reserve arising on the investment in Regeneron, which was reclassified to profit or loss in accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates), of which €2 million (net of tax) related to hedges of net investments in foreign operations in 2020.

D.15.8. Stock options

Stock option plans awarded and measurement of stock option plans

No stock options were awarded during 2021 or 2020.

Stock options awarded in 2019 are summarized below, with the assumptions used to determine their fair value:

	2019
Date of Board meeting approving the plan	April 30, 2019
Total number of options granted	220,000
Exercise price (€)	76.71
Vesting period	4 years
Plan expiry date	April 30, 2029
Fair value of the plan (€ million)	2
Fair value per option granted (€)	7.80
Assumptions used to determine fair value	
Dividend yield	4.31%
Volatility of Sanofi shares, computed on a historical basis	22.48%
Risk-free interest rate	0.15%
Plan maturity	8 years

The expense recognized through equity for stock option plans is immaterial.

Stock subscription option plans

Details of the terms of exercise of stock subscription options granted under the various plans are presented below in Sanofi share equivalents. These plans were awarded to certain corporate officers and employees of Sanofi companies.

The table shows all Sanofi stock subscription option plans still outstanding or under which options were exercised in the year ended December 31, 2021:

Source	Date of grant	Number of options granted	Start date of exercise period	Expiry date	Exercise price (€)	Number of options outstanding as of 12/31/2021
Sanofi-aventis	03/09/2011	874,500	03/10/2015	03/09/2021	50.48	—
Sanofi-aventis	03/05/2012	814,050	03/06/2016	03/05/2022	56.44	63,948
Sanofi	03/05/2013	788,725	03/06/2017	03/05/2023	72.19	355,230
Sanofi	03/05/2014	1,009,250	03/06/2018	03/05/2024	73.48	611,672
Sanofi	06/24/2015	435,000	06/25/2019	06/24/2025	89.38	339,964
Sanofi	05/04/2016	402,750	05/05/2020	05/04/2026	75.90	284,150
Sanofi	05/10/2017	378,040	05/11/2021	05/10/2027	88.97	294,220
Sanofi	05/02/2018	220,000	05/03/2022	05/02/2028	65.84	168,784
Sanofi	04/30/2019	220,000	05/02/2023	04/30/2029	76.71	220,000
Total						**2,337,968**

The exercise of all outstanding stock subscription options would increase shareholders' equity by approximately €180 million. The exercise of each option results in the issuance of one share.

Summary of stock option plans

A summary of stock options outstanding at each balance sheet date, and of movements during the relevant periods, is presented below:

	Number of options	Weighted average exercise price per share (€)	Total (€ million)
Options outstanding at January 1, 2019	**6,849,573**	**61.81**	**423**
Options exercisable	*5,468,214*	*56.80*	*311*
Options granted	220,000	76.71	17
Options exercised	(2,816,123)	53.18	(150)
Options cancelled[(a)]	(48,005)	72.84	(3)
Options forfeited	(383,425)	44.90	(17)
Options outstanding at December 31, 2019	**3,822,020**	**70.58**	**270**
Options exercisable	*2,650,375*	*67.14*	*178*
Options exercised	(868,655)	59.20	(52)
Options cancelled[(a)]	(91,305)	87.73	(8)
Options forfeited	(282,790)	54.12	(15)
Options outstanding at December 31, 2020	**2,579,270**	**75.61**	**195**
Options exercisable	*1,845,050*	*74.51*	*137*
Options exercised	(190,076)	59.53	(11)
Options cancelled[(a)]	(51,216)	65.84	(3)
Options forfeited	(10)	50.48	—
Options outstanding at December 31, 2021	**2,337,968**	**77.13**	**180**
Options exercisable	*1,949,184*	*78.15*	*152*

(a) Mainly due to the grantees leaving Sanofi.

The table below provides summary information about options outstanding and exercisable as of December 31, 2021:

	Outstanding			Exercisable	
Range of exercise prices per share	Number of options	Weighted average residual life (years)	Weighted average exercise price per share (€)	Number of options	Weighted average exercise price per share (€)
From €50.00 to €60.00 per share	63,948	0.18	56.44	63,948	56.44
From €60.00 to €70.00 per share	168,784	6.34	65.84	—	—
From €70.00 to €80.00 per share	1,471,052	3.13	74.12	1,251,052	73.66
From €80.00 to €90.00 per share	634,184	4.35	89.19	634,184	89.19
Total	**2,337,968**			**1,949,184**	

D.15.9. Number of shares used to compute diluted earnings per share

Diluted earnings per share is computed using the number of shares outstanding plus stock options with dilutive effect and restricted shares.

(million)	2021	2020	2019
Average number of shares outstanding	1,252.5	1,253.6	1,249.9
Adjustment for stock options with dilutive effect	0.3	0.4	0.8
Adjustment for restricted shares	5.1	6.1	6.4
Average number of shares used to compute diluted earnings per share	**1,257.9**	**1,260.1**	**1,257.1**

In 2021, 0.6 million stock options were not taken into account in computing diluted earnings per share because they had no dilutive effect, compared with 0.6 million in 2020 and 0.8 million in 2019.

D.16. Non-controlling interests

Non-controlling interests did not represent a material component of Sanofi's consolidated financial statements in the years ended December 31, 2021, 2020 and 2019.

D.17. Debt, cash and cash equivalents and lease liabilities

D.17.1. Debt, cash and cash equivalents

Changes in Sanofi's financial position during the period were as follows:

(€ million)	2021	2020	2019
Long-term debt	17,123	19,745	20,131
Short-term debt and current portion of long-term debt	3,183	2,767	4,554
Interest rate and currency derivatives used to manage debt	(56)	119	(117)
Total debt	**20,250**	**22,631**	**24,568**
Cash and cash equivalents	(10,098)	(13,915)	(9,427)
Interest rate and currency derivatives used to manage cash and cash equivalents	(169)	74	(34)
Net debt[a]	**9,983**	**8,790**	**15,107**

(a) Net debt does not include lease liabilities, which amounted to €2,108 million as of December 31, 2021, €1,163 million as of December 31, 2020, and €1,248 million as of December 31, 2019 (see the maturity analysis at Note D.17.2.).

"Net debt" is a non-GAAP financial measure used by management and investors to measure Sanofi's overall net indebtedness.

Reconciliation of carrying amount to value on redemption

(€ million)	Carrying amount at December 31, 2021	Amortized cost	Adjustment to debt measured at fair value	Value on redemption		
				December 31, 2021	December 31, 2020	December 31, 2019
Long-term debt	17,123	58	(5)	17,176	19,794	20,180
Short-term debt and current portion of long-term debt	3,183	2	(2)	3,183	2,767	4,553
Interest rate and currency derivatives used to manage debt	(56)	–	11	(45)	142	(86)
Total debt	**20,250**	**60**	**4**	**20,314**	**22,703**	**24,647**
Cash and cash equivalents	(10,098)			(10,098)	(13,915)	(9,427)
Interest rate and currency derivatives used to manage cash and cash equivalents	(169)			(169)	74	(34)
Net debt	**9,983**	**60**	**4**	**10,047**	**8,862**	**15,186**

a) Principal financing transactions during the year

The table below shows the movement in total debt during the period:

(€ million)	December 31, 2020	Cash flows from financing activities		Non-cash items				December 31, 2021
		Repayments	New borrowings	Other cash flows	Currency translation differences [a]	Reclassification from non-current to current	Other items[b]	
Long-term debt	19,745	(38)	—	—	124	(2,704)	(4)	17,123
Short-term debt and current portion of long-term debt	2,767	(2,203)	—	(615)	248	2,704	282	3,183
Interest rate and currency derivatives used to manage debt	119	—	—	(197)	9	—	13	(56)
Total debt	**22,631**	**(2,241)**	**—**	**(812)**	**381**	**—**	**291**	**20,250**

(a) These amounts include unrealized gains and losses, and the impact of foreign currency translation of the financial statements of subsidiaries outside the Euro zone.

(b) These amounts include (i) effects of changes in the scope of consolidation, amounting to €299 million; (ii) movements in accrued interest; and (iii) fair value remeasurements.

Sanofi did not carry out any bond issues in 2021.

Two bond issues were redeemed during 2021:

- a March 2011 bond issue of $2 billion, which matured on March 29, 2021; and
- a September 2015 bond issue of €500 million, repaid on June 22, 2021 in advance of the contractual maturity date.

As of December 31, 2021 Sanofi had two syndicated credit facilities of €4 billion each available for the purposes of current operations, each of them linked to environmental and social indicators. The maturity of one facility was extended to December 4, 2022 following the exercise of an extension option in June 2021, and the maturity of the other was extended to December 7, 2026 following the exercise of an extension option in October 2021. Both facilities still have a one-year extension option.

In line with Sanofi's commitment to embed sustainable development in the "Play to Win" strategy, the two revolving credit facilities build in an adjustment mechanism that links the credit spread to the attainment of two sustainable development performance indicators: Sanofi's contribution to polio eradication, and the reduction in Sanofi's carbon footprint.

The tables below show the movement in total debt during prior periods:

		Cash flows from financing activities		Non-cash items				
(€ million)	December 31, 2019	Repayments	New borrowings	Other cash flows	Currency translation differences [a]	Reclassification from non-current to current	Other items[b]	December 31, 2020
Long-term debt	20,131	—	2,019	—	(152)	(2,285)	32	19,745
Short-term debt and current portion of long-term debt	4,554	(3,952)	—	86	(219)	2,285	13	2,767
Interest rate and currency derivatives used to manage debt	(117)	—	—	196	(14)	—	54	119
Total debt	**24,568**	**(3,952)**	**2,019**	**282**	**(385)**	**—**	**99**	**22,631**

		Cash flows from financing activities		Non-cash items				
(€ million)	December 31, 2018	Repayments	New borrowings	Other cash flows	Currency translation differences [a]	Reclassification from non-current to current	Other items[b]	December 31, 2019
Long-term debt	22,007	(12)	1,997	—	93	(3,964)	10	20,131
Short-term debt and current portion of long-term debt	2,633	(2,055)	—	24	14	3,964	(26)	4,554
Interest rate and currency derivatives used to manage debt	(54)	—	—	(177)	130	—	(16)	(117)
Total debt	**24,586**	**(2,067)**	**1,997**	**(153)**	**237**	**—**	**(32)**	**24,568**

(a) These amounts include unrealized gains and losses, and the impact of foreign currency translation of the financial statements of subsidiaries outside the Euro zone.

(b) These amounts include movements in accrued interest and fair value remeasurements.

b) Net debt by type, at value on redemption

	2021			2020			2019		
(€ million)	Non-current	Current	Total	Non-current	Current	Total	Non-current	Current	Total
Bond issues	17,118	2,828	19,946	19,698	2,280	21,978	20,128	4,079	24,207
Other bank borrowings	21	163	184	96	200	296	40	156	196
Other borrowings	37	3	40	–	2	2	13	12	25
Bank credit balances	–	189	189	–	285	285	–	305	305
Interest rate and currency derivatives used to manage debt	–	(45)	(45)	57	85	142	–	(86)	(86)
Total debt	**17,176**	**3,138**	**20,314**	**19,851**	**2,852**	**22,703**	**20,181**	**4,466**	**24,647**
Cash and cash equivalents	–	(10,098)	(10,098)	–	(13,915)	(13,915)	–	(9,427)	(9,427)
Interest rate and currency derivatives used to manage cash and cash equivalents	–	(169)	(169)	6	68	74	(6)	(28)	(34)
Net debt[a]	**17,176**	**(7,129)**	**10,047**	**19,857**	**(10,995)**	**8,862**	**20,175**	**(4,989)**	**15,186**

(a) Net debt does not include lease liabilities (see the maturity schedule in Note D.17.2.).

Bond issues carried out by Sanofi under the Euro Medium Term Note (EMTN) program are as follows:

Issuer	ISIN code	Issue date	Maturity	Annual interest rate	Amount (€ million)
Sanofi	FR0011625433	November 2013	November 2023	2.5%	1,000
Sanofi	FR0012146777	September 2014	March 2022	1.125%	1,000
Sanofi	FR0012146801	September 2014	September 2026	1.75%	1,510
Sanofi	FR0012969038	September 2015	September 2025	1.5%	750
Sanofi	FR0013143997	April 2016	April 2024	0.625%	600
Sanofi	FR0013144003	April 2016	April 2028	1.125%	700
Sanofi	FR0013201621	September 2016	September 2022	- %	850
Sanofi	FR0013201639	September 2016	January 2027	0.5%	1,150
Sanofi	FR0013505104	March 2020	April 2025	1%	1,000
Sanofi	FR0013505112	March 2020	April 2030	1.5%	1,000
Sanofi	FR0013324332	March 2018	March 2023	0.5%	1,750
Sanofi	FR0013324340	March 2018	March 2026	1%	1,500
Sanofi	FR0013324357	March 2018	March 2030	1.375%	2,000
Sanofi	FR0013324373	March 2018	March 2038	1.875%	1,250
Sanofi	FR0013409836	March 2019	March 2022	- %	850
Sanofi	FR0013409844	March 2019	March 2029	0.875%	650
Sanofi	FR0013409851	March 2019	March 2034	1.25%	500

Bond issues carried out by Sanofi under the public bond issue program (shelf registration statement) registered with the US Securities and Exchange Commission (SEC) comprise:

Issuer	ISIN code	Issue date	Maturity	Annual interest rate	Amount ($ million)
Sanofi	US801060AC87	June 2018	June 2023	3.375%	1,000
Sanofi	US801060AD60	June 2018	June 2028	3.625%	1,000

The “Other borrowings” line mainly comprises participating shares issued between 1983 and 1987, of which 76,986 remain outstanding, with a nominal amount of €12 million.

In order to manage its liquidity needs for current operations, as of December 31, 2021 Sanofi has:

- a syndicated credit facility of €4 billion, drawable in euros and in US dollars, the maturity of which has been extended to December 4, 2022 following the exercise of an initial extension option in June 2021, and with a further one-year extension option still available; and
- a syndicated credit facility of €4 billion, drawable in euros and in US dollars, the maturity of which has been extended to December 7, 2026 following the exercise of an initial extension option in October 2021, and with a further one-year extension option still available.

Sanofi also has a €6 billion Negotiable European Commercial Paper program in France and a $10 billion Commercial Paper program in the United States. During 2021 only the US program was used, with an average drawdown of $2.3 billion (versus a maximum of $4.0 billion). As of December 31, 2021, there were no drawdowns under any of those programs.

The financing in place as of December 31, 2021 at the level of the holding company (which manages most of Sanofi’s financing needs centrally) is not subject to any financial covenants, and contains no clauses linking spreads or fees to the credit rating.

c) Debt by maturity, at value on redemption

December 31, 2021		Current	Non-current				
(€ million)	Total	2022	2023	2024	2025	2026	2027 and later
Bond issues	19,946	2,828	3,629	600	1,750	4,160	6,979
Other bank borrowings	184	163	18	2	1	–	—
Other borrowings	40	3	–	–	–	–	37
Bank credit balances	189	189	–	–	–	–	–
Interest rate and currency derivatives used to manage debt	(45)	(45)	–	–	–	–	–
Total debt	**20,314**	**3,138**	**3,647**	**602**	**1,751**	**4,160**	**7,016**
Cash and cash equivalents	(10,098)	(10,098)	–	–	–	–	–
Interest rate and currency derivatives used to manage cash and cash equivalents	(169)	(169)	–	–	–	–	–
Net debt[(a)]	**10,047**	**(7,129)**	**3,647**	**602**	**1,751**	**4,160**	**7,016**

(a) Net debt does not include lease liabilities, which amounted to €2,108 million as of December 31, 2021 as of December 31, 2021; €1,163 million as of December 31, 2020; and €1,248 million as of December 31, 2019 (see the maturity analysis at Note D.17.2.).

As of December 31, 2021, the main undrawn confirmed general-purpose credit facilities at holding company level amounted to €8 billion, half of which expires in 2022 and half in 2026.

As of December 31, 2021, no single counterparty represented more than 6% of Sanofi's undrawn confirmed credit facilities.

December 31, 2020		Current	Non-current				
(€ million)	Total	2021	2022	2023	2024	2025	2026 and later
Bond issues	21,978	2,280	2,700	3,569	600	1,750	11,079
Other bank borrowings	296	200	73	6	2	6	9
Finance lease obligations	–	–	–	–	–	–	–
Other borrowings	2	2	–	–	–	–	–
Bank credit balances	285	285	–	–	–	–	–
Interest rate and currency derivatives used to manage debt	142	85	57	–	–	–	–
Total debt	**22,703**	**2,852**	**2,830**	**3,575**	**602**	**1,756**	**11,088**
Cash and cash equivalents	(13,915)	(13,915)	–	–	–	–	–
Interest rate and currency derivatives used to manage cash and cash equivalents	74	68	6	–	–	–	–
Net debt	**8,862**	**(10,995)**	**2,836**	**3,575**	**602**	**1,756**	**11,088**

December 31, 2019		Current	Non-current				
(€ million)	Total	2020	2021	2022	2023	2024	2025 and later
Bond issues	24,207	4,079	2,284	2,700	3,642	600	10,902
Other bank borrowings	196	156	6	6	23	5	–
Finance lease obligations	–	–	–	–	–	–	–
Other borrowings	25	12	–	–	–	–	13
Bank credit balances	305	305	–	–	–	–	–
Interest rate and currency derivatives used to manage debt	(86)	(86)	–	–	–	–	–
Total debt	**24,647**	**4,466**	**2,290**	**2,706**	**3,665**	**605**	**10,915**
Cash and cash equivalents	(9,427)	(9,427)	–	–	–	–	–
Interest rate and currency derivatives used to manage cash and cash equivalents	(34)	(28)	(6)	–	–	–	–
Net debt	**15,186**	**(4,989)**	**2,284**	**2,706**	**3,665**	**605**	**10,915**

d) Debt by interest rate, at value on redemption

The table below splits net debt between fixed and floating rate, and by maturity, as of December 31, 2021. The figures shown are values on redemption, before the effects of derivative instruments:

(€ million)	Total	2022	2023	2024	2025	2026	2027 and later
Fixed-rate debt	19,946	2,828	3,629	600	1,750	4,160	6,979
of which euro	*18,188*						
of which US dollar	*1,758*						
% fixed-rate	**98%**						
Floating-rate debt	413	355	18	2	1	–	37
of which euro	*56*						
of which US dollar	*18*						
% floating-rate	**2%**						
Debt	**20,359**	**3,183**	**3,647**	**602**	**1,751**	**4,160**	**7,016**
Cash and cash equivalents	(10,098)	(10,098)	–	–	–	–	–
of which euro	*(6,548)*						
of which US dollar	*(3,005)*						
% floating-rate	**100%**						
Net debt	**10,261**	**(6,915)**	**3,647**	**602**	**1,751**	**4,160**	**7,016**

Sanofi issues debt in two currencies, the euro and the US dollar, and also invests its cash and cash equivalents in those currencies. Sanofi also operates cash pooling arrangements to manage the surplus cash and short-term liquidity needs of foreign subsidiaries located outside the euro zone.

To optimize the cost of debt or reduce the volatility of debt and manage its exposure to financial foreign exchange risk, Sanofi uses derivative instruments (interest rate swaps, currency swaps, foreign exchange swaps and forward contracts) that alter the fixed/floating rate split and the currency split of its net debt:

(€ million)	Total	2022	2023	2024	2025	2026	2027 and later
Fixed-rate debt	17,612	494	3,629	600	1,750	4,160	6,979
of which euro	*14,820*						
of which US dollar	*2,792*						
% fixed-rate	**87%**						
Floating-rate debt	2,702	2,644	18	2	1	–	37
of which euro	*(429)*						
of which US dollar	*898*						
of which Japanese yen	*302*						
% floating-rate	**13%**						
Debt	**20,314**	**3,138**	**3,647**	**602**	**1,751**	**4,160**	**7,016**
Cash and cash equivalents	(10,267)	(10,267)	–	–	–	–	–
of which euro	*(1,261)*						
of which US dollar	*(4,359)*						
of which Singapore dollar	*(2,912)*						
% floating-rate	**100%**						
Net debt	**10,047**	**(7,129)**	**3,647**	**602**	**1,751**	**4,160**	**7,016**

The table below shows the fixed/floating rate split of net debt at value on redemption after taking account of derivative instruments as of December 31, 2020 and December 31, 2019:

(€ million)	2020	%	2019	%
Fixed-rate debt	20,713	91%	21,713	88%
Floating-rate debt	1,990	9%	2,934	12%
Debt	**22,703**	**100%**	**24,647**	**100%**
Cash and cash equivalents	(13,841)		(9,461)	
Net debt	**8,862**		**15,186**	

The weighted average interest rate on debt as of December 31, 2021 was 1.4% before derivative instruments and 1.9% after derivative instruments. Cash and cash equivalents were invested as of December 31, 2021 at an average rate of 0.1% before derivative instruments and 0.9% after derivative instruments.

The projected full-year sensitivity of net debt to interest rate fluctuations for 2022 is as follows:

Change in short-term interest rates	Impact on pre-tax net income (€ million)	Impact on pre-tax income/(expense) recognized directly in equity (€ million)
+100 bp	74	–
+25 bp	19	–
-25 bp	(19)	–
-100 bp	(74)	–

e) Debt by currency, at value on redemption

The table below shows net debt by currency at December 31, 2021, before and after derivative instruments contracted to convert the foreign-currency net debt of exposed entities into their functional currency:

(€ million)	Before derivative instruments	After derivative instruments
Euro	11,696	13,129
US dollar	(1,229)	(669)
Singapore dollar	(2)	(2,912)
Mexican peso	–	302
Pound sterling	–	271
Other currencies	(205)	(74)
Net debt	**10,261**	**10,047**

The table below shows net debt by currency at December 31, 2020 and 2019, after derivative instruments contracted to convert the foreign currency net debt of exposed entities into their functional currency:

(€ million)	2020	2019
Euro	13,725	17,691
US dollar	(3,304)	(813)
Other currencies	(1,559)	(1,692)
Net debt	**8,862**	**15,186**

f) Market value of net debt

The market value of Sanofi's debt, net of cash and cash equivalents and derivatives and excluding accrued interest, is as follows:

(€ million)	2021	2020	2019
Market value	11,024	10,500	16,370
Value on redemption	10,047	8,862	15,186

The fair value of debt is determined by reference to quoted market prices at the balance sheet date in the case of quoted instruments (level 1 in the IFRS 7 hierarchy, see Note D.12.), and by reference to the fair value of interest rate and currency derivatives used to manage net debt (level 2 in the IFRS 7 hierarchy, see Note D.12.).

g) Future contractual cash flows relating to debt and related derivatives

The table below shows the amount of future undiscounted contractual cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt:

December 31, 2021		Payments due by period					
(€ million)	Total	2022	2023	2024	2025	2026	2027 and later
Debt	**21,728**	**3,330**	**3,826**	**791**	**1,937**	**3,176**	**8,668**
Principal	20,086	3,055	3,588	601	1,751	3,011	8,080
Interest[(a)]	1,642	275	238	190	186	165	588
Net cash flows related to derivative instruments	**(51)**	**(59)**	**(1)**	**2**	**2**	**2**	**3**
Total	**21,677**	**3,271**	**3,825**	**793**	**1,939**	**3,178**	**8,671**

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2021.

Future contractual cash flows are shown on the basis of the carrying amount in the balance sheet at the reporting date, without reference to any subsequent management decision that might materially alter the structure of Sanofi's debt or its hedging policy.

The tables below show the amount of future undiscounted contractual cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt as of December 31, 2020 and 2019:

December 31, 2020		Payments due by period					
(€ million)	Total	2021	2022	2023	2023	2025	2026 and later
Debt	**24,339**	**2,943**	**3,019**	**3,808**	**791**	**1,937**	**11,841**
Principal	22,392	2,622	2,757	3,571	601	1,751	11,090
Interest[(a)]	1,947	321	262	237	190	186	751
Net cash flows related to derivative instruments	**163**	**135**	**28**	**–**	**–**	**–**	**–**
Total	**24,502**	**3,078**	**3,047**	**3,808**	**791**	**1,937**	**11,841**

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2020.

December 31, 2019		Payments due by period					
(€ million)	Total	2020	2021	2022	2023	2023	2025 and later
Debt	**26,708**	**4,775**	**2,588**	**2,952**	**3,862**	**771**	**11,760**
Principal	24,596	4,417	2,305	2,710	3,646	604	10,914
Interest[(a)]	2,112	358	283	242	216	167	846
Net cash flows related to derivative instruments	**(117)**	**(97)**	**(11)**	**(9)**	**—**	**—**	**—**
Total	**26,591**	**4,678**	**2,577**	**2,943**	**3,862**	**771**	**11,760**

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2019.

D.17.2. Lease liabilities

A maturity analysis of lease liabilities as of December 31, 2021, 2020 and 2019 is set forth below:

		Undiscounted future minimum lease payments				
(€ million)	Total	Less than 1 year	From 1 to 3 years	From 3 to 5 years	More than 5 years	Discounting effect
Total lease liabilities as of December 31, 2021	**2,108**	**314**	**476**	**362**	**1,184**	**(228)**
Total lease liabilities as of December 31, 2020	**1,163**	**247**	**357**	**225**	**482**	**(148)**
Total lease liabilities as of December 31, 2019	**1,248**	**272**	**422**	**232**	**540**	**(218)**

Lease liabilities as of December 31, 2021 include leases relating to real estate assets located at Cambridge, MA (United States), as described in Note D.3., which have a lease term of 15 years.

D.18. Liabilities related to business combinations and to non-controlling interests

For a description of the nature of the liabilities reported in the line item ***Liabilities related to business combinations and to non-controlling interests***, refer to Note B.8.5. The principal acquisitions are described in Notes D.1. and D.2.

The liabilities related to business combinations and to non-controlling interests shown in the table below are level 3 instruments under the IFRS 7 fair value hierarchy (see Note D.12.) except for the CVRs issued in connection with the acquisition of Genzyme, which are level 1 instruments.

Movements in liabilities related to business combinations and to non-controlling interests are shown below:

(€ million)	Liabilities related to non-controlling interests[a]	CVRs issued in connection with the acquisition of Genzyme[b]	Bayer contingent consideration arising from the acquisition of Genzyme	MSD contingent consideration (European Vaccines business)	Shire contingent consideration arising from the acquisition of Translate Bio	Other	Total[c]
Balance at January 1, 2019	**22**	**99**	**472**	**410**	**—**	**301**	**1,304**
Payments made	—	—	(113)	(69)	—	(55)	(237)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount)[d]	—	49	(214)	38	—	81	(46)
Other movements	(22)	(153)	—	—	—	(73)	(248)
Currency translation differences	—	5	11	6	—	5	27
Balance at December 31, 2019	**—**	**—**	**156**	**385**	**—**	**259**	**800**
Payments made	—	—	(42)	(78)	—	(2)	(122)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount)[d]	—	—	9	9	—	(53)	(35)
Other movements	—	—	(8)	—	—	(2)	(10)
Currency translation differences	—	—	(11)	(4)	—	(13)	(28)
Balance at December 31, 2020	**—**	**—**	**104**	**312**	**—**	**189**	**605**
New transactions[e]	—	—	—	—	323	37	360
Payments made[f]	—	—	(31)	(75)	—	(152)	(258)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount)[d]	—	—	(18)	26	19	(31)	(4)
Other movements	—	—	—	—	—	(14)	(14)
Currency translation differences	—	—	4	6	12	3	25
Balance at December 31, 2021	**—**	**—**	**59**	**269**	**354**	**32**	**714**

(a) Includes put options granted to non-controlling interests that expired in 2019.

(b) Based on the quoted market price per CVR of $0.72 as of October 30, 2019 and $0.48 as of December 31, 2018. The CVR agreement was terminated in March 2020 following signature of a litigation settlement agreement.

(c) Portion due after more than one year: €577 million as of December 31, 2021 (€387 million as of December 31, 2020 and €508 million as of December 31, 2019); portion due within less than one year: €137 million as of December 31, 2021 (€218 million as of December 31, 2020 and €292 million as of December 31, 2019).

*(d) Amounts reported within the income statement line item **Fair value remeasurement of contingent consideration**, and mainly comprising unrealized gains and losses.*

(e) Mainly corresponds to the recognition of the Shire Human Genetic Therapies Inc. (Shire) contingent consideration liability of $382 million resulting from the acquisition of Translate Bio in September 2021.

(f) The "Other" column mainly relates to the contingent consideration liability due to True North Therapeutics as a result of Sanofi's acquisition of Bioverativ which was settled in the first half of 2021.

As of December 31, 2021, ***Liabilities related to business combinations and to non-controlling interests*** mainly comprised:

- the Bayer contingent consideration liability arising from Sanofi's acquisition of Genzyme in 2011. As of December 31, 2021, Bayer was still entitled to receive the following potential payments:
  - a percentage of sales of alemtuzumab up to a maximum of $1,250 million or over a maximum period of 10 years, whichever is achieved first,
  - milestone payments subject to the attainment of specified levels of worldwide sales of alemtuzumab beginning in 2021.

  The fair value of this liability was measured at €59 million as of December 31, 2021, compared with €104 million as of December 31, 2020 and €156 million as of December 31, 2019. The fair value of the Bayer liability is determined by applying the contractual terms to sales projections which have been weighted to reflect the probability of success, and discounted. If the discount rate were to fall by one percentage point, the fair value of the Bayer liability would increase by approximately 1%;
- the MSD contingent consideration liability arising from the 2016 acquisition of the Sanofi Pasteur activities carried on within the former Sanofi Pasteur MSD joint venture, which amounted to €269 million as of December 31, 2021, €312 million as of December 31, 2020 and €385 million as of December 31, 2019 (see Note D.12.). The fair value of this contingent consideration is determined by applying the royalty percentage stipulated in the contract to discounted sales projections. If the discount rate were to fall by one percentage point, the fair value of the MSD contingent consideration liability would increase by approximately 2%;
- a contingent consideration liability towards Shire Human Genetic Therapies Inc. (Shire) arising from Sanofi's acquisition of Translate Bio in September 2021.

  In a December 2016 business combination predating the acquisition of control by Sanofi, Translate Bio (then called Rana Therapeutics, Inc.) acquired from Shire the intellectual property rights relating to the latter's Messenger RNA Therapeutics (MRT) program.

As of December 31, 2021, Shire was entitled to receive the following potential payments:

– milestone payments contingent on the launch of products based on MRT technology, and on the attainment of a specified level of sales of those products, and

– a percentage of sales of those products.

The fair value of the Shire liability was measured at €354 million as of December 31, 2021; it was determined by applying the contractual terms to development and sales projections which were weighted to reflect the probability of success, and discounted. If the discount rate were to fall by one percentage point, the fair value of the Shire liability would increase by approximately 14%.

The table below sets forth the maximum amount of contingent consideration payable:

December 31, 2021		Payments due by period			
(€ million)	Total	Less than 1 year	From 1 to 3 years	From 3 to 5 years	More than 5 years
Commitments relating to contingent consideration in connection with business combinations[(a)]	689	108	181	78	322

(a) Includes €0.4 billion for the Bayer contingent consideration and €0.3 billion for the MSD contingent consideration.

The nominal amount of contingent consideration was €1,043 million as of December 31, 2020 and €3,503 million as of December 31, 2019. The reduction in commitments during 2020 mainly reflects the termination of the CVR agreement in March 2020.

D.19. Provisions, income tax liabilities and other liabilities

The line item ***Non current provisions and other non-current liabilities*** comprises the following:

(€ million)	2021	2020 [(a)]	2019 [(a)]
Provisions	6,430	6,998	7,125
Other non-current liabilities[(b)]	291	317	288
Total	**6,721**	**7,315**	**7,413**

(a) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (IAS 19, Employee Benefits) (see note A.2.1.).
(b) Includes derivative financial instruments: €6 million as of December 31, 2021, €92 million as of December 31, 2020, €10 million as of December 31, 2019.

Non-current income tax liabilities are described in Note D.19.4., and other current liabilities in Note D.19.5.

The table below sets forth movements in non-current provisions for the reporting periods presented:

(€ million)	Provisions for pensions and other post-employment benefits (D.19.1.) [d]	Provisions for other long-term benefits	Restructuring provisions (D.19.2.)	Other provisions (D.19.3.)	Total
Balance at January 1, 2019	**3,291**	**761**	**632**	**1,968**	**6,652**
Changes in scope of consolidation	(1)	—	—	—	(1)
Increases in provisions	262 [a]	189	393	554 [b]	1,398
Provisions utilized	(285) [a]	(102)	(3)	(132)	(522)
Reversals of unutilized provisions	(205) [a]	(3)	(15)	(511) [c]	(734)
Transfers	92	(3)	(411)	168	(154)
Net interest related to employee benefits, and unwinding of discount	78	5	3	18	104
Currency translation differences	35	8	1	6	50
Actuarial gains and losses on defined-benefit plans	331	—	—	—	331
Balance at December 31, 2019	**3,599**	**855**	**600**	**2,071**	**7,125**
Changes in scope of consolidation	(3)	—	—	8	5
Increases in provisions	256 [a]	169	688	369	1,482
Provisions utilized	(566) [a]	(109)	(5)	(113)	(793)
Reversals of unutilized provisions	(226) [a]	(5)	(42)	(245)	(518)
Transfers	12	—	(369)	(64)	(421)
Net interest related to employee benefits, and unwinding of discount	55	2	1	8	66
Currency translation differences	(117)	(33)	(5)	(59)	(214)
Actuarial gains and losses on defined-benefit plans	266	—	—	—	266
Balance at December 31, 2020	**3,276**	**879**	**868**	**1,975**	**6,998**
Changes in scope of consolidation	(2)	—	—	37	35
Increases in provisions	247 [a]	156	67	261	731
Provisions utilized	(222) [a]	(122)	(8)	(107)	(459)
Reversals of unutilized provisions	(13) [a]	(7)	(35)	(145)	(200)
Transfers	(13)	(3)	(370)	(39)	(425)
Net interest related to employee benefits, and unwinding of discount	42	2	—	9	53
Currency translation differences	80	30	2	33	145
Actuarial gains and losses on defined-benefit plans	(448)	—	—	—	(448)
Balance at December 31, 2021	**2,947**	**935**	**524**	**2,024**	**6,430**

(a) In the case of "Provisions for pensions and other post-employment benefits", the "Increases in provisions" line corresponds to rights vesting in employees during the period, and past service cost; the "Provisions utilized" line corresponds to contributions paid into pension funds, and plan settlements; and the "Reversals of unutilized provisions" line corresponds to plan curtailments, settlements and amendments.

(b) Amounts charged during the period include changes to estimates of future expenditures on environmental risks.

(c) This amount mainly comprises a reversal of a provision resulting from a settlement of litigation (see Note D.28.).

(d) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (see Note A.2.1.).

D.19.1. Provisions for pensions and other post-employment benefits

Sanofi offers its employees pension plans and other post-employment benefit plans. The specific features of the plans (benefit formulas, fund investment policy and fund assets held) vary depending on the applicable laws and regulations in each country where the employees work. These employee benefits are accounted for in accordance with IAS 19 (see Note B.23.).

Sanofi's pension obligations in four major countries represented approximately 88% of the total value of the defined-benefit obligation and approximately 87% of the total value of plan assets as of December 31, 2021. The features of the principal defined-benefit plans in each of those four countries are described below.

France

Lump-sum retirement benefit plans

All employees working for Sanofi in France are entitled on retirement to a lump-sum payment, the amount of which depends both on their length of service and on the rights guaranteed by collective and internal agreements. The employee's final salary is used in calculating the amount of these lump-sum retirement benefits. These plans represent approximately 36% of Sanofi's total obligation in France.

Defined-benefit pension plans

These plans provide benefits from the date of retirement. Employees must fulfil a number of criteria to be eligible for these benefits. All of these plans are now closed, the only plan still open to new entrants having been closed in 2019. These plans represent approximately 64% of Sanofi's total obligation in France.

Germany

Top-up defined-benefit pension plan

The benefits offered under this pension plan are wholly funded by the employer (there are no employee contributions) via a Contractual Trust Agreement (CTA), under which benefits are estimated on the basis of a career average salary. Employees are entitled to receive an annuity under this plan if their salary exceeds the social security ceiling. The amount of the pension is calculated by reference to a range of vesting rates corresponding to salary bands. The plan also includes disability and death benefits. This plan represents approximately 63% of Sanofi's total obligation in Germany.

Sanofi-Aventis plus (SAV plus)

A top-up pension plan (SAV plus) replaced a previous top-up defined-benefit plan. New entrants joining the plan after April 1, 2015 contribute to a defined-contribution plan that is partially funded via the company's CTA.

All employees whose salary exceeds the social security ceiling are automatically covered by the plan. The employer's contribution is 15% of the amount by which the employee's salary exceeds the social security ceiling.

Multi-employer plan (Pensionskasse)

This is a defined-benefit plan treated as a defined-contribution plan, in accordance with the accounting policies described in Note B.23. Currently, contributions cover the level of annuities. Only the portion relating to the future revaluation of the annuities is included in the defined-benefit pension obligation. The obligation relating to this revaluation amounted to €877 million as of December 31, 2021, versus €773 million as of December 31, 2020 and €694 million as of December 31, 2019. This plan represents approximately 25% of Sanofi's total defined-benefit obligation in Germany.

United States

Defined-benefit pension plans

In the United States, there are two types of defined-benefit plan:

- "Qualified" plans within the meaning of the Employee Retirement Income Security Act of 1974 (ERISA), which provide guaranteed benefits to eligible employees during retirement, and in the event of death or disability. Employees can elect to receive a reduced annuity, in exchange for an annuity to be paid in the event of their death to a person designated by them. An annuity is also granted under the plan if the employee dies before retirement age. Eligible employees do not pay any contributions. These plans are closed to new entrants, and the vesting of rights for future service periods is partially frozen. These plans represent approximately 55% of Sanofi's total obligation in the United States;
- "Non-qualified" plans within the meaning of ERISA provide top-up retirement benefits to some eligible employees depending on the employee's level of responsibility and subject to a salary cap. These plans represent approximately 12% of Sanofi's total obligation in the United States.

Healthcare cover and life insurance

Sanofi companies provide some eligible employees with healthcare cover and life insurance during the retirement period (the company's contributions are capped at a specified level). These plans represent approximately 33% (or €696 million) of Sanofi's total obligation and 4% (or €42 million) of total plan assets in the United States.

United Kingdom

Defined-benefit pension plans

Sanofi operates a number of pension plans in the United Kingdom that reflect past acquisitions. The most significant arrangements are defined-benefit plans that have been closed since October 1, 2015. With effect from that date, employees can no longer pay into these plans.

Under these defined-benefit plans, an annuity is paid from the retirement date. This annuity is calculated on the basis of the employee's length of service as of September 30, 2015, and of the employee's final salary (or salary on the date he or she leaves Sanofi).

The rates used for the vesting of rights vary from member to member. For most members, rights vest at the rate of 1.25% or 1.50% of final salary for each qualifying year of service giving entitlement. The notional retirement age varies according to the category to which the member belongs, but in most cases retirement is at age 65. Members may choose to retire before or after the notional retirement age (60 years), in which case the amount of the annual pension is adjusted to reflect the revised estimate of the length of the retirement phase. Pensions are usually indexed to the Retail Price Index (RPI). Members paid a fixed-percentage contribution into their pension plan (the percentage varied according to the employee category), and the employer topped up the contribution to the required amount. These plans represent approximately 100% of Sanofi's total obligation in the United Kingdom.

For service periods subsequent to October 1, 2015, employees belong to a new defined-contribution plan.

Actuarial assumptions used to measure Sanofi's obligations

Actuarial valuations of Sanofi's benefit obligations were computed by management with assistance from external actuaries as of December 31, 2021, 2020 and 2019.

Those calculations were based on the following financial and demographic assumptions:

	2021				2020				2019			
	France	Germany	USA	UK	France	Germany	USA	UK	France	Germany	USA	UK
Discount rate[a][b]	0.10% to 1.10%	0.10% to 1.10%	2.70%	1.90%	—% or 0.55%	—% or 0.55%	2.40%	1.35%	0.25% or 0.75%	0.25% or 0.75%	3.00%	2.00%
General inflation rate[c]	1.95%	1.95%	—	3.30%	1.45%	1.45%	—	2.95%	1.30%	1.30%	—	2.85%
Pension benefit indexation	1.95%	1.95%	—	3.15%	1.45%	1.45%	—	2.85%	1.25% to 2.25%	1.30%	—	2.80%
Healthcare cost inflation rate	—	— [d]	3.50% to 4.50%	— [d]	—	— [d]	3.50% to 4.50%	— [d]	2.00%	— [d]	5.52%	— [d]
Retirement age	62 to 67	62	55 to70	60 to 65	62 to 67	62	55 to 70	60 to 65	62 to 67	62	55 to 70	60 to 65
Mortality table	TGH/ TGF 05	Heubeck RT 2018 G	RP2012 Proj. MP2020 White Collar	SAPS S3	TGH/ TGF 05	Heubeck RT 2018 G	RP2012 Proj. G. Scale MP2019 White Collar	SAP S S2	TGH/ TGF 05	Heubeck RT 2018 G	RP2014 G. Scale MP2018	SAPS S2

(a) The discount rates used were based on market rates for high quality corporate bonds with a duration close to that of the expected benefit payments under the plans. The benchmarks used to determine discount rates were the same for all periods presented.

(b) The rate depends on the duration of the plan (0 to 7 years, 7 to 10 years, or more than 10 years).

(c) Inflation for the euro zone is determined using a multi-criterion method.

(d) No post-employment healthcare benefits are provided in France since 2020, Germany and UK.

Weighted average duration of obligation for pensions and other long-term benefits in principal countries

The table below shows the duration of Sanofi's obligations in the principal countries:

	2021				2020				2019			
(years)	France	Germany	USA	UK	France	Germany	USA	UK	France	Germany	USA	UK
Weighted average duration	12	16	15	17	13	16	16	18	13	15	14	17

Sensitivity analysis

The table below shows the sensitivity of Sanofi's obligations for pensions and other post-employment benefits to changes in key actuarial assumptions:

(€ million)		Pensions and other post-employment benefits, by principal country			
Measurement of defined-benefit obligation	Change in assumption	France	Germany	USA	UK
Discount rate	-0.50%	+100	+275	+161	+296
General inflation rate	+0.50%	+61	+359	—	+164
Pension benefit indexation	+0.50%	+67	+350	—	+116
Healthcare cost inflation rate	+0.50%	—	—	+15	—
Mortality table	+1 year	+47	+84	+53	+150

The table below reconciles the net obligation in respect of Sanofi's pension and other post-employment benefit plans with the amounts recognized in the consolidated financial statements:

	Pensions and other post-employment benefits		
(€ million)	2021	2020 [a]	2019 [a]
Measurement of the obligation:			
Beginning of period	12,456	13,094	11,824
Current service cost	227	221	205
Interest cost	148	192	289
Actuarial losses/(gains) due to changes in demographic assumptions	(162)	52	(61)
Actuarial losses/(gains) due to changes in financial assumptions	(210)	936	1,431
Actuarial losses/(gains) due to experience adjustments	(120)	(26)	(115)
Plan amendments, curtailments or settlements not specified in the terms of the plan[a]	(4)	(938)	(212)
Plan settlements specified in the terms of the plan	(66)	(75)	(78)
Benefits paid	(503)	(545)	(504)
Changes in scope of consolidation and transfers	(8)	(12)	13
Currency translation differences	417	(443)	302
Obligation at end of period	**12,175**	**12,456**	**13,094**
Fair value of plan assets:			
Beginning of period	9,358	9,651	8,610
Interest income on plan assets	106	138	211
Difference between actual return and interest income on plan assets	207	696	926
Administration costs	(7)	(14)	(7)
Plan settlements specified in the terms of the plan	(66)	(75)	(78)
Plan settlements not specified in the terms of the plan	(9)	(739)	(64)
Contributions from plan members	6	6	6
Employer's contributions	176	490	250
Benefits paid	(458)	(469)	(470)
Changes in scope of consolidation and transfers	(6)	—	—
Currency translation differences	344	(326)	267
Fair value of plan assets at end of period	**9,651**	**9,358**	**9,651**
Net amount shown in the balance sheet:			
Net obligation	2,524	3,098	3,443
Effect of asset ceiling	15	1	1
Net amount shown in the balance sheet at end of period	**2,539**	**3,099**	**3,444**
Amounts recognized in the balance sheet:			
Pre-funded obligations (see Note D.7.)[c]	(408)	(177)	(155)
Obligations provided for	2,947	3,276	3,599
Net amount recognized at end of period	**2,539**	**3,099**	**3,444**
Benefit cost for the period:			
Current service cost	227	221	205
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan[b]	5	(199)	(148)
Net interest (income)/cost	42	55	78
Contributions from plan members	(6)	(7)	(6)
Administration costs and taxes paid during the period	7	14	7
Expense recognized directly in profit or loss	**276**	**84**	**136**
Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses) [d]	(685)	266	331
Expense/(gain) for the period	**(409)**	**350**	**467**

(a) These amounts include the impact of applying the April 2021 IFRIC agenda decision on the attribution of benefits to periods of service. The effect of this decision is a €231 million decrease in the provision originally recognized as of January 1, 2019, mainly in respect of lump-sum retirement benefits in France. Prior to the IFRIC agenda decision, such benefits were allocated to periods of service starting on the date the employee joined the company, whereas they are now allocated starting on the date from which each subsequent year of service counts towards entitlement to the benefit.

(b) For 2019, this line mainly comprises the favorable impact of the amendment to the remaining top-up pension plan, following the application of the Pacte law in France. For 2020, it mainly comprises a reduction in post-employment benefit liabilities following the announcement of voluntary redundancy programs, primarily in Europe.

(c) For 2021, this line includes €220 million of assets in the United Kingdom.That amount is not subject to any asset ceiling, in accordance with IFRIC 14.

(d) Amounts recognized in Other Comprehensive Income (see Note D.15.7.).

The tables below show Sanofi's net liability in respect of pension plans and other post-employment benefits by geographical region:

(€ million)	Pensions and other post-employment benefits by geographical region					
December 31, 2021	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Measurement of obligation	1,657	3,576	2,099	3,414	1,429	12,175
Fair value of plan assets	838	2,808	1,127	3,629	1,249	9,651
Effect of asset ceiling	—	—	—	—	(15)	(15)
Net amount shown in the balance sheet at end of period	**819**	**768**	**972**	**(215)**	**195**	**2,539**

(€ million)	Pensions and other post-employment benefits by geographical region					
December 31, 2020	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Measurement of obligation	1,778	3,580	2,091	3,561	1,446	12,456
Fair value of plan assets	906	2,661	1,077	3,536	1,178	9,358
Effect of asset ceiling	—	—	—	—	(1)	(1)
Net amount shown in the balance sheet at end of period	**872**	**919**	**1,014**	**25**	**269**	**3,099**

(€ million)	Pensions and other post-employment benefits by geographical region					
December 31, 2019	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Measurement of obligation	1,849	3,470	2,948	3,388	1,439	13,094
Fair value of plan assets	956	2,516	1,774	3,258	1,147	9,651
Effect of asset ceiling	—	—	—	—	(1)	(1)
Net amount shown in the balance sheet at end of period	**893**	**954**	**1,174**	**130**	**293**	**3,444**

The table below shows the fair value of plan assets relating to Sanofi's pension and other post-employment plans, split by asset category:

	2021	**2020**	**2019**
Securities quoted in an active market	**86.9%**	**94.8%**	**87.4%**
Cash and cash equivalents	0.7%	3.5%	1.8%
Equity instruments	25.0%	24.8%	22.6%
Bonds and similar instruments	53.8%	59.9%	55.8%
Real estate	4.0%	3.4%	3.8%
Commodities	1.0%	0.9%	0.9%
Other	2.4%	2.3%	2.5%
Other securities	**13.1%**	**5.2%**	**12.6%**
Hedge funds	—%	0.4%	—%
Insurance policies	13.1%	4.8%	12.6%
Total	**100.0%**	**100.0%**	**100.0%**

Sanofi has a long-term objective of maintaining or increasing the extent to which its pension obligations are covered by assets. To this end, Sanofi uses an asset-liability management strategy, matching plan assets to its pension obligations. This policy aims to ensure the best fit between the assets held on the one hand, and the associated liabilities and expected future payments to plan members on the other. To meet this aim, Sanofi operates a risk monitoring and management strategy (mainly focused on interest rate risk and inflation risk), while investing a growing proportion of assets in high-quality bonds with comparable maturities to those of the underlying obligations and in contracts entered into with leading insurance companies to fund certain post-employment benefit obligations.

The tables below show the service cost for Sanofi's pension and other post-employment benefit plans, by geographical region:

(€ million)	Pensions and other post-employment benefits by geographical region					
Service cost for 2021	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Current service cost	72	47	57	—	51	227
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan	2	—	—	3	—	5
Net interest cost/(income) including administration costs and taxes paid during the period	5	5	27	3	9	49
Contributions from plan members	—	—	—	—	(6)	(6)
Expense/(gain) recognized directly in profit or loss	**80**	**52**	**84**	**6**	**54**	**276**
Remeasurement of net defined-benefit (asset)/ liability (actuarial gains and losses)	(106)	(113)	(157)	(236)	(73)	(685)
Expense/(gain) for the period	**(26)**	**(61)**	**(73)**	**(230)**	**(19)**	**(409)**

(€ million)	Pensions and other post-employment benefits by geographical region					
Service cost for 2020	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Current service cost	65	49	51	—	56	221
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan	(87)	10	(123)	—	1	(199)
Net interest cost/(income) including administration costs and taxes paid during the period	7	13	34	5	10	69
Contributions from plan members	—	—	—	—	(7)	(7)
Expense/(gain) recognized directly in profit or loss	**(15)**	**72**	**(38)**	**5**	**60**	**84**
Remeasurement of net defined-benefit (asset)/ liability (actuarial gains and losses)	23	121	22	115	(15)	266
Expense/(gain) for the period	**8**	**193**	**(16)**	**120**	**45**	**350**

(€ million)	Pensions and other post-employment benefits by geographical region					
Service cost for 2019	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Current service cost	68	42	42	—	53	205
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan	(146)	13	(12)	(2)	(1)	(148)
Net interest cost/(income) including administration costs and taxes paid during the period	16	17	40	2	11	86
Contributions from plan members	—	—	—	—	(6)	(6)
Expense/(gain) recognized directly in profit or loss	**(62)**	**72**	**70**	**—**	**56**	**136**
Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)	42	(4)	148	133	12	331
Expense/(gain) for the period	**(20)**	**68**	**218**	**133**	**68**	**467**

An analysis of the "Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)" line in the preceding tables is set forth below:

	2021				2020				2019			
(€ million)	**France**	**Germany**	**USA**	**UK**	**France**	**Germany**	**USA**	**UK**	**France**	**Germany**	**USA**	**UK**
Actuarial gains/(losses) arising during the period	106	113	156	237	(23)	(121)	(22)	(115)	(42)	5	(148)	(133)
Comprising:												
Gains/(losses) on experience adjustments[(a)]	60	182	23	35	28	76	214	341	145	331	210	242
Gains/(losses) on demographic assumptions	—	—	51	125	9	—	(42)	(14)	—	—	—	63
Gains/(losses) on financial assumptions	46	(69)	82	77	(60)	(197)	(194)	(442)	(187)	(326)	(358)	(438)

(a) Experience adjustments are mainly due to the effect of trends in the financial markets on plan assets.

The net pre-tax actuarial loss (excluding investments accounted for using the equity method) recognized directly in equity is presented below:

(€ million)	2021	2020	2019
Net pre-tax actuarial loss	(2,738)	(3,423)	(3,160)

The present value of Sanofi's obligations in respect of pension and other post-employment benefit plans at the end of each reporting period is shown below:

(€ million)	2021	2020	2019
Present value of wholly or partially funded obligations in respect of pension and other post-employment benefit plans	11,069	11,322	11,829
Present value of unfunded obligations	1,106	1,134	1,265
Total	**12,175**	**12,456**	**13,094**

The total expense for pensions and other post-employment benefits (€276 million in 2021) is allocated between income statement line items as follows:

(€ million)	2021	2020	2019
Cost of sales	77	77	70
Research and development expenses	65	63	30
Selling and general expenses	87	88	104
Other operating (income)/expenses, net	(1)	(140)	(109)
Restructuring costs	6	(59)	(37)
Financial expenses	42	55	78
Total	**276**	**84**	**136**

The estimated amounts of employer's contributions to plan assets in 2022 are as follows:

(€ million)	France	Germany	USA	UK	Other	Total
Employer's contributions in 2021 (estimate):						
2022	—	—	—	4	45	49

The table below shows the expected timing of benefit payments under pension and other post-employment benefit plans for future years:

(€ million)	France	Germany	USA	UK	Other	Total
2022	93	186	106	126	55	566
2023	65	189	98	130	56	538
2024	72	194	97	134	56	553
2025	76	197	99	139	57	568
2026	77	199	92	143	61	572
2027 to 2029	487	992	469	788	350	3,086

The table below shows estimates as of December 31, 2021 for the timing of future payments in respect of unfunded pension and other post-employment benefit plans:

		Payments due by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Estimated payments	1,106	60	105	106	835

D.19.2. Restructuring provisions

The table below shows movements in restructuring provisions classified in non-current and current liabilities:

(€ million)	2021	2020	2019
Balance, beginning of period	**1,499**	**1,390**	**1,572**
Of which:			
• Classified in non-current liabilities	868	600	632
• Classified in current liabilities	631	790	940
Change in provisions recognized in profit or loss for the period	183	767	760
Provisions utilized	(571)	(663)	(897)
Transfers	1	20	(51)
Unwinding of discount	—	1	3
Currency translation differences	6	(16)	3
Balance, end of period	**1,118**	**1,499**	**1,390**
Of which:			
• Classified in non-current liabilities	524	868	600
• Classified in current liabilities	594	631	790

Provisions for employee termination benefits as of December 31, 2021 amounted to €943 million (compared with €1,260 million as of December 31, 2020 and €1,125 million as of December 31, 2019).

The provisions apply mainly to France, and relate to various voluntary redundancy programs:

- collectively-agreed termination programs involving a number of legal entities were announced at the end of June 2020 as part of the rollout of the “Play to Win” strategy; these include an end-of-career paid leave plan and an end-of-career transition plan, and were still ongoing during 2021. In addition, Sanofi-Aventis Recherche & Développement (i) announced a voluntary redundancy program in 2020 in connection with the reorganization of R&D operations in France, which was implemented in 2021, and (ii) signed a collectively-agreed termination program in 2021 as part of the rollout of the “Play to Win” strategy; these programs, which cover support functions, include an end-of-career paid leave plan and an end-of-career transition plan;
- programs were announced in 2019 relating to (i) R&D (Sanofi-Aventis Recherche & Développement), and (ii) sales forces (the "SAF 2019" plan implemented by Sanofi-Aventis France);
- collectively-agreed termination programs were announced in 2018 relating to reorganization of support functions (“Horizon 2020” plan);
- the program announced in 2016 in connection with Sanofi's new strategic roadmap (the “Forward” plan) was substantively completed as of December 31, 2021.

The remainder of the provision for France comprises termination benefits associated with previously-announced programs (early retirement plans and end-of-career transition plans).

The provision includes the present values of:

- gross annuities for self-funded plans;
- employer’s social security charges on early retirement annuities for all plans (outsourced and self-funded);
- the levy charged on those annuities under the “Fillon” law (only for plans with termination of employment contracts).

The average residual holding periods under these plans were 1.94 years, 1.99 years and 1.72 years as of December 31, 2021, 2020 and 2019, respectively.

Restructuring provisions as of December 31, 2021 include €12 million relating to the rollout in various geographies of Sanofi's "New Business Model", which involves the use of local distributors rather than a direct presence in certain countries. There is also a residual provision of €63 million (versus €110 million as of December 31, 2020) relating to the transfer to Evotec of the infectious diseases early-stage R&D portfolio and research unit.

The main other countries covered by restructuring provisions are Germany, Japan and the United States.

The timing of future termination benefit payments is as follows:

December 31, 2021		Benefit payments by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Employee termination benefits					
• France	614	269	288	53	4
• Other countries	329	207	106	14	2
Total	**943**	**476**	**394**	**67**	**6**

December 31, 2020		Benefit payments by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Employee termination benefits					
• France	889	295	457	124	13
• Other countries	371	195	149	18	9
Total	**1,260**	**490**	**606**	**142**	**22**

December 31, 2019		Benefit payments by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Employee termination benefits					
• France	694	314	268	110	2
• Other countries	431	343	79	6	3
Total	**1,125**	**657**	**347**	**116**	**5**

D.19.3. Other provisions

Other provisions include provisions for risks and litigation relating to environmental, tax, commercial and product liability matters.

(€ million)	2021	2020	2019
Environmental risks	650	713	737
Product liability risks, litigation and other	1,374	1,262	1,334
Total	**2,024**	**1,975**	**2,071**

Provisions for environmental risks relate primarily to contingencies arising from business divestitures, and include remediation costs relating to such environmental risks.

Identified environmental risks are covered by provisions estimated on the basis of the costs Sanofi believes it will be obliged to meet over a period not exceeding (other than in exceptional cases) 30 years. Sanofi expects that €65 million of those provisions will be utilized in 2022, and €267 million over the period from 2023 through 2026.

"Product liability risks, litigation and other" mainly comprises provisions for risks relating to product liability (including IBNR provisions as described in Note B.12.), government investigations, regulatory or antitrust law claims, contingencies arising from business divestitures (other than environmental risks), and remediation costs related to leases.

The main pending legal and arbitral proceedings and government investigations are described in Note D.22.

A full risk and litigation assessment is performed with the assistance of Sanofi's legal advisers, and provisions are recorded as required by circumstances in accordance with the principles described in Note B.12.

D.19.4. Non-current income tax liabilities

Non-current income tax liabilities amounted to €2,039 million as of December 31, 2021 (versus €1,733 million as of December 31, 2020 and €1,680 million as of December 31, 2019).

The estimated tax charge on deemed repatriation attributable to the accumulated earnings of non-US operations and payable over 8 years is recognized as a liability, and amounted to €960 million in 2021 versus €894 million in 2020 and €974 million in 2019. The resulting residual tax charge generated a non-current liability of €576 million as of December 31, 2021, versus €569 million in 2020 and €649 million in 2019. In accordance with Sanofi accounting policies, this non-current liability is not discounted.

Non-current income tax liabilities include uncertainties over income tax treatments amounting to €1,463 million as of December 31, 2021, versus €1,164 million as of December 31, 2020 and €1,031 million as of December 31, 2019.

A US legal restructuring resulted in a capital loss of €2.9 billion recognized in the 2020 final tax filing. One-third of the capital loss has been used against 2020 capital gains and the remaining balance will be eligible to carry back for three years. Due to management's judgement about potential alternative interpretations of the prevailing tax law, no tax benefit has been recognized on this transaction in accordance with IFRIC 23.

D.19.5. Current provisions and other current liabilities

Current provisions and other current liabilities comprise the following:

(€ million)	2021	2020	2019
Taxes payable, other than corporate income taxes	428	347	361
Employee-related liabilities	2,126	2,042	1,978
Restructuring provisions (see Note D.19.2.)	594	631	790
Interest rate derivatives (see Note D.20.)	1	—	2
Currency derivatives (see Note D.20.)	62	205	87
Equity derivatives (see Note D.20.)	16	—	—
Amounts payable for acquisitions of non-current assets	559	467	413
Customer contract liabilities[(a)]	319	252	—
Other current liabilities[(b)]	7,112	6,188	6,072
Total	**11,217**	**10,132**	**9,703**

(a) See Note A.7., "Agreements relating to the recombinant COVID-19 vaccine candidate developed by Sanofi in collaboration with GSK'.

(b) "Other current liabilities" includes provisions for customer rebates and returns, and for discounts and rebates granted to healthcare authorities and governmental programs (see Note D.23.). As of December 31, 2019, the "Other current liabilities" line also included $315 million deposited by Sanofi in an escrow account, the release of which occurred in March 2020 following the signature of a settlement agreement in the CVR litigation between Sanofi and the Trustee.

D.20. Derivative financial instruments and market risks

The table below shows the fair value of derivative instruments as of December 31, 2021, 2020 and 2019:

(€ million)	Non-current assets	Current assets	Total assets	Non-current liabilities	Current liabilities	Total liabilities	Market value at December 31, 2021 (net)	Market value at December 31, 2020 (net)	Market value at December 31, 2019 (net)
Currency derivatives	–	284	284	–	(62)	(62)	222	(209)	103
operating	–	*33*	*33*	–	*(23)*	*(23)*	10	*7*	*(15)*
financial	–	*251*	*251*	–	*(39)*	*(39)*	212	*(216)*	*118*
Interest rate derivatives	3	11	14	(6)	(1)	(7)	7	20	27
Equity derivatives	–	–	–	–	(16)	(16)	(16)	(26)	(4)
Total	**3**	**295**	**298**	**(6)**	**(79)**	**(85)**	**213**	**(215)**	**126**

Objectives of the use of derivative financial instruments

Sanofi uses derivative instruments to manage operating exposure to movements in exchange rates, and financial exposure to movements in interest rates and exchange rates (where the debt or receivable is not contracted in the functional currency of the borrower or lender entity). On occasion, Sanofi uses equity derivatives in connection with the management of its portfolio of equity investments.

Sanofi performs periodic reviews of its transactions and contractual agreements in order to identify any embedded derivatives, which are accounted for separately from the host contract in accordance with IFRS 9. Sanofi had no material embedded derivatives as of December 31, 2021, 2020 or 2019.

Counterparty risk

For a description of counterparty risk, refer to "–Item 11. — Quantitative and Qualitative Disclosures about Market Risk".

a) Currency derivatives used to manage operating risk exposures

For a description of Sanofi's objectives, policies and procedures for the management of operating foreign exchange risk, refer to "–Item 11. — Quantitative and Qualitative Disclosures about Market Risk".

The table below shows operating currency hedging instruments in place as of December 31, 2021, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2021			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
(€ million)	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
Forward currency sales	**3,912**	**4**	**–**	**–**	**–**	**3,912**	**4**
of which US dollar	*1,392*	*5*	*–*	*–*	*–*	*1,392*	*5*
of which Chinese yuan renminbi	*665*	*(2)*	*–*	*–*	*–*	*665*	*(2)*
of which Singapore dollar	*355*	*(1)*	*–*	*–*	*–*	*355*	*(1)*
of which Japanese yen	*199*	*3*	*–*	*–*	*–*	*199*	*3*
of which Taiwan dollar	*122*	*(1)*	*–*	*–*	*–*	*122*	*(1)*
Forward currency purchases	**2,374**	**6**	**–**	**–**	**–**	**2,374**	**6**
of which US dollar	*833*	*(2)*	*–*	*–*	*–*	*833*	*(2)*
of which Singapore dollar	*696*	*7*	*–*	*–*	*–*	*696*	*7*
of which Chinese yuan renminbi	*255*	*—*	*–*	*–*	*–*	*255*	*—*
of which Hungarian forint	*77*	*—*	*–*	*–*	*–*	*77*	*—*
of which Russian rouble	*72*	*(1)*	*–*	*–*	*–*	*72*	*(1)*
Total	**6,286**	**10**	**–**	**–**	**–**	**6,286**	**10**

The table below shows operating currency hedging instruments in place as of December 31, 2020, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2020			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
(€ million)	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
Forward currency sales	**3,477**	**7**	**—**	**—**	**—**	**3,477**	**7**
of which US dollar	*1,367*	*10*	*—*	*—*	*—*	*1,367*	*10*
of which Chinese yuan renminbi	*521*	*2*	*—*	*—*	*—*	*521*	*2*
of which Singapore dollar	*287*	*(1)*	*—*	*—*	*—*	*287*	*(1)*
of which Japanese yen	*143*	*1*	*—*	*—*	*—*	*143*	*1*
of which Mexican peso	*121*	*—*	*—*	*—*	*—*	*121*	*—*
Forward currency purchases	**1,932**	**—**	**—**	**—**	**—**	**1,932**	**—**
of which US dollar	*580*	*(1)*	*—*	*—*	*—*	*580*	*(1)*
of which Singapore dollar	*571*	*(1)*	*—*	*—*	*—*	*571*	*(1)*
of which Chinese yuan renminbi	*286*	*1*	*—*	*—*	*—*	*286*	*1*
of which Russian rouble	*61*	*—*	*—*	*—*	*—*	*61*	*—*
of which Japanese yen	*55*	*—*	*—*	*—*	*—*	*55*	*—*
Total	**5,409**	**7**	**—**	**—**	**—**	**5,409**	**7**

The table below shows operating currency hedging instruments in place as of December 31, 2019, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2019			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
(€ million)	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
Forward currency sales	**3,372**	**(10)**	**–**	**–**	**–**	**3,372**	**(10)**
of which US dollar	*1,186*	*3*	*–*	*–*	*–*	*1,186*	*3*
of which Chinese yuan renminbi	*447*	*—*	*–*	*–*	*–*	*447*	*—*
of which Singapore dollar	*410*	*—*	*–*	*–*	*–*	*410*	*—*
of which Russian rouble	*184*	*(3)*	*–*	*–*	*–*	*184*	*(3)*
of which Saudi riyal	*133*	*1*	*–*	*–*	*–*	*133*	*1*
Forward currency purchases	**1,835**	**(5)**	**–**	**–**	**–**	**1,835**	**(5)**
of which US dollar	*602*	*(6)*	*–*	*–*	*–*	*602*	*(6)*
of which Singapore dollar	*525*	*1*	*–*	*–*	*–*	*525*	*1*
of which Chinese yuan renminbi	*130*	*—*	*–*	*–*	*–*	*130*	*—*
of which Hungarian forint	*60*	*—*	*–*	*–*	*–*	*60*	*—*
of which Russian rouble	*49*	*—*	*–*	*–*	*–*	*49*	*—*
Total	**5,207**	**(15)**	**–**	**–**	**–**	**5,207**	**(15)**

b) Currency and interest rate derivatives used to manage financial exposure

For a description of Sanofi's objectives, policies and procedures for the management of financial foreign exchange risk and interest rate risk, refer to "–Item 11. — Quantitative and Qualitative Disclosures about Market Risk".

The table below shows financial currency hedging instruments in place, with the notional amount translated into euros at the relevant closing exchange rate:

	2021			2020			2019		
(€ million)	Notional amount	Fair value	Expiry	Notional amount	Fair value	Expiry	Notional amount	Fair value	Expiry
Forward currency sales	**7,655**	**15**		**5,064**	**10**		**8,513**	**40**	
of which US dollar	*5,384* (a)	*23*	*2022*	*3,721*	*20*	*2021*	*6,330*	*51*	*2020*
of which Hungarian forint	*756* (b)	*4*	*2022*	*13*		*2021*	*93*	*—*	*2020*
of which Brazilian real	*95* (c)	*(3)*	*2022*	*–*	*–*	*2021*	*16*	*—*	*2020*
Forward currency purchases	**9,293**	**197**		**9,004**	**(226)**		**10,968**	**78**	
of which US dollar	*4,816* (d) (e)	*128*	*2022*	*6,068*	*(200)*	*2022*	*7,363*	*42*	*2020*
of which Singapore dollar	*2,910* (f)	*75*	*2022*	*2,250*	*(27)*	*2021*	*2,332*	*32*	*2020*
of which Hungarian forint	*865*	*(5)*	*2022*	*9*		*2021*	*29*	*—*	*2020*
Total	**16,948**	**212**		**14,068**	**(216)**		**19,481**	**118**	

(a) Includes forward sales with a notional amount of $3,615 million expiring in 2022, designated as a hedge of Sanofi's net investment in Bioverativ. As of December 31, 2021, the fair value of these forward contracts represented an asset of €20 million; the opposite entry was recognized in "Other comprehensive income", with the impact on financial income and expense being immaterial.

(b) Includes forward sales with a notional amount of HUF 279 billion expiring in 2022, designated as a hedge of Sanofi's net investment in Chinoin. As of December 31, 2021, the fair value of these forward contracts represented an asset of €2 million; the opposite entry was recognized in "Other comprehensive income", with the impact on financial income and expense being immaterial.

(c) Includes forward sales with a notional amount of BRL 600 million expiring in 2022, designated as a hedge of Sanofi's net investment in Medley Farmaceutica. As of December 31, 2021, the fair value of these forward contracts represented a liability of €3 million; the opposite entry was recognized in "Other comprehensive income", with the impact on financial income and expense being immaterial.

(d) Includes forward purchases with a notional amount of $550 million expiring in 2022, designated as a fair value hedge of the exposure of $550 million of bond issues to fluctuations in the EUR/USD spot rate. As of December 31, 2021, the fair value of the contracts was an asset of €19 million, the opposite entry for €0.1 million of which was credited to "Other comprehensive income" under the cost of hedging accounting treatment.

(e) Includes currency swaps with a notional amount of $1,000 million, receive 0.22% pay EUR -0.63% expiring in 2022, designated as a cash flow hedge of $1,000 million of bond issues. As of December 31, 2021, the fair value of the swaps was an asset of €23 million.

(f) Includes forward purchases with a notional amount of SGD1,000 million expiring in 2022, designated as a fair value hedge of the exposure of an equivalent amount of intragroup current accounts to fluctuations in the EUR/SGD spot rate. As of December 31, 2021, the fair value of the contracts was an asset of €20 million, the opposite entry for €1.5 million of which was debited to "Other comprehensive income" under the cost of hedging accounting treatment.

The table below shows interest rate hedging instruments in place as of December 31, 2021:

	Notional amounts by expiry date as of December 31, 2021								Of which designated as fair value hedges		Of which designated as cash flow hedges		
(€ million)	2022	2023	2024	2025	2026	2027 and later	Total	Fair value	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
pay capitalized Eonia / receive 0.06%	2,000	—	—	—	—	—	2,000	10	2,000	10	—	—	—
pay -0.57% / receive capitalized Eonia	600	—	—	—	—	—	600	1	—	—	600	1	—
pay SOFR USD / receive 1.03%	—	—	—	—	—	440	440	(5)	440	—	—	—	—
pay SOFR USD / receive 1.32%	—	—	—	—	—	440	440	3	440	3	—	—	—
receive capitalized Eonia / pay 1.48%[(a)]	42	57	—	—	—	—	99	(3)	99	(3)	—	—	—
Total	**2,642**	**57**	**—**	**—**	**—**	**880**	**3,579**	**7**	**2,979**	**6**	**600**	**1**	**—**

(a) These interest rate swaps hedge fixed-rate bonds with a nominal of €99 million held in a Professional Specialized Investment Fund dedicated to Sanofi and recognized within "Loans, advances and other long-term receivables" (see Note D.7.).

The table below shows interest rate hedging instruments in place as of December 31, 2020:

	Notional amounts by expiry date as of December 31, 2020								Of which designated as fair value hedges		Of which designated as cash flow hedges		
(€ million)	2021	2022	2023	2024	2025	2026	Total	Fair value	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
pay 1.81% / receive 3-month US dollar Libor	—	2,000	—	—	—	—	2,000	23	2,000	23	—	—	—
pay 3-month US dollar Libor / receive 2.22%	—	600	—	—	—	—	600	1	—	—	600	1	1
receive capitalized Eonia / pay 1.48%[(a)]	—	42	57	—	—	—	99	(4)	99	(4)	—	—	—
Total	**—**	**2,642**	**57**	**—**	**—**	**—**	**2,699**	**20**	**2,099**	**19**	**600**	**1**	**1**

(a) These interest rate swaps hedge fixed-rate bonds with a nominal of €99 million held in a Professional Specialized Investment Fund dedicated to Sanofi and recognized within "Loans, advances and other long-term receivables" (see Note D.7.).

The table below shows interest rate hedging instruments in place as of December 31, 2019:

	Notional amounts by expiry date as of December 31, 2019								Of which designated as fair value hedges		Of which designated as cash flow hedges		
(€ million)	2020	2021	2022	2023	2024	2025	Total	Fair value	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
pay capitalized Eonia / receive 1.58%	—	—	2,000	—	—	—	2,000	28	2,000	28	—	—	—
pay capitalized Eonia / receive 0.06%	—	—	600	—	—	—	600	3	—	—	600	3	3
pay 1.81% / receive 3-month US dollar Libor	446	—	—	—	—	—	446	(2)	—	—	446	(2)	—
pay 3-month US dollar Libor / receive 2.22%	446	—	—	—	—	—	446	4	446	4	—	—	—
receive capitalized Eonia / pay 1.48%[(a)]	—	—	42	57	—	—	99	(6)	99	(6)	—	—	—
Total	**892**	**—**	**2,642**	**57**	**—**	**—**	**3,591**	**27**	**2,545**	**26**	**1,046**	**1**	**3**

(a) These interest rate swaps hedge fixed-rate bonds with a nominal of €99 million held in a Professional Specialized Investment Fund dedicated to Sanofi and recognized within "Loans, advances and other long-term receivables" (see Note D.7.).

c) Equity derivatives

During 2019, Sanofi contracted derivative instruments (collars) on 593,712 shares of Dexcom Inc; the collars were designated as fair value hedges of the Dexcom shares. As of December 31, 2021 they had a negative fair value of €16 million, recognized in full in ***Other comprehensive income***.

d) Actual or potential effects of netting arrangements

The table below is prepared in accordance with the accounting policies described in Note B.8.3.:

	2021		2020		2019	
(€ million)	Derivative financial assets	Derivative financial liabilities	Derivative financial assets	Derivative financial liabilities	Derivative financial assets	Derivative financial liabilities
Gross carrying amounts before offset (a)	298	(85)	82	(297)	225	(99)
Gross amounts offset (in accordance with IAS 32) (b)	—	—	—	—	—	—
Net amounts as reported in the balance sheet (a) - (b) = (c)	**298**	**(85)**	**82**	**(297)**	**225**	**(99)**
Effects of other netting arrangements (not fulfilling the IAS 32 criteria for offsetting) (d)	—	—				
Financial instruments	(67)	67	(81)	81	(89)	89
Fair value of financial collateral	N/A	N/A	N/A	N/A	N/A	N/A
Net exposure (c) + (d)	**231**	**(18)**	**1**	**(216)**	**136**	**(10)**

D.21. Off balance sheet commitments

The off balance sheet commitments presented below are shown at their nominal value.

D.21.1. Off balance sheet commitments relating to operating activities

Off balance sheet commitments relating to Sanofi's operating activities comprise the following:

December 31, 2021		Payments due by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Leases with a term of less than 12 months, low value asset leases and lease contracts committed but not yet commenced[a][b]	109	39	16	18	36
Irrevocable purchase commitments[c]					
• given[d]	8,901	5,343	1,784	685	1,089
• received	(1,124)	(366)	(442)	(166)	(150)
Research and development license agreements - commitments given					
• commitments related to R&D and other commitments[e]	536	254	169	77	36
• contingent milestone payments in connection with development programs in progress[f]	2,892	237	1,139	451	1,065
Total - net commitments given[g]	**11,314**	**5,507**	**2,666**	**1,065**	**2,076**

(a) Includes future variable lease payments not recognized in Lease liabilities as of December 31, 2021. As of December 31, 2020, the amount of such commitments was €950 million. The year-on-year movement is largely related to two leases of real estate assets at Cambridge, MA (United States); (see Note D.3.2.).

(b) Lease commitments given to joint ventures were immaterial as of December 31, 2021.

(c) These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down-payments (see Note D.3.) and (ii) goods and services. As of December 31, 2020, irrevocable commitments amounted to €7,153 million given and €(608) million received.

(d) Irrevocable purchase commitments given as of December 31, 2021 include €987 million of commitments to joint ventures.

(e) Commitments related to R&D, and other commitments, amounted to €500 million as of December 31, 2020.

(f) This line includes only contingent milestone payments on development projects in progress. The increase relative to December 31, 2020 (when this figure amounted to €2,456 million) is mainly due to a license agreement entered into with Biond Biologics and to the acquisition of Kadmon.

(g) This line excludes:

(i) commitments given relating to projects in the research phase (€6.7 billion in 2021, €6.7 billion in 2020) and payments contingent upon the attainment of sales targets once a product is commercialized (€8.1 billion in 2021, €8.1 billion in 2020);

(ii) commitments received in respect of the additional share of quarterly profits to which Sanofi is entitled under the collaboration agreements with Regeneron on monoclonal antibodies (capped at 10% of Regeneron's share of quarterly profits), until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration (see Note C.1.). Such commitments received were €2.9 billion in 2021 (€2.6 billion in 2020), relative to cumulative development costs of €7.6 billion as of December 31, 2020; and

(iii) other commitments received amounting to €5.8 billion as of December 31, 2021 (€2.7 billion as of December 31, 2020), mainly comprising discovery, development and commercialization agreements with partners further to the acquisitions of Ablynx (€1.0 billion as of December 31, 2021, €1.1 billion as of December 31, 2020) and of Kymab (€0.5 billion as of December 31, 2021, see Note D.1.), plus contingent consideration receivable based on attainment of regulatory and sales milestones for commercialized products under the terms of licenses or rights assignment agreements amounting to €4.2 billion as of December 31, 2021 and €1.6 billion as of December 31, 2020.

In pursuance of its strategy, Sanofi may acquire technologies and rights to products. Such acquisitions may be made in various contractual forms: acquisitions of shares, loans, license agreements, joint development, and co-marketing. These arrangements generally involve upfront payments on signature of the agreement, development milestone payments, and royalties. Some of these complex agreements include undertakings to fund research programs in future years and payments contingent upon achieving specified development milestones, the granting of approvals or licenses, or the attainment of sales targets once a product is commercialized.

The "Research and development license agreements" line comprises future service commitments to fund research and development or technology, and probable contingent milestone payments regarded as reasonably achievable (i.e. all potential milestone payments relating to projects in the development phase, for which the future financial consequences are known or probable and for which there is a sufficiently reliable estimate).

The major agreements entered into by Sanofi in 2021 are described below:

- in January 2021, Sanofi entered into a license agreement with Biond Biologics, a biopharmaceutical company developing novel immunotherapies for cancer and a platform enabling the intra-cellular delivery of biologics, for the development and commercialization of BND-22 (a humanized IgG4 antagonist antibody targeting the Ig-like transcript 2 (ILT2) receptor, in development for the treatment of solid tumors). Under the terms of the agreement, Sanofi made an upfront payment of $125 million, and could pay up to $1 billion contingent on the attainment of certain objectives;
- on April 8, 2021, Sanofi acquired the entire share capital of Kymab. The acquisition price includes milestone payments of up to $350 million contingent on the attainment of certain development objectives (see Note D.1.);
- on April 9, 2021, Sanofi acquired Tidal Therapeutics. The acquisition price includes milestone payments of up to $310 million contingent on the attainment of certain development objectives (see Note D.1.);
- on July 6, 2021, Sanofi entered into a license agreement with Eureka Therapeutics and Memorial Sloan Kettering Cancer Center (MSK) for the treatment of multiple myeloma. Under the terms of the agreement, Sanofi could pay up to $1 billion contingent on the attainment of certain objectives;
- on November 18, 2021, Sanofi entered into a strategic collaboration with Owkin around R&D programs targeting four types of cancer, involving an upfront payment by Sanofi of $90 million spread over three years, plus further milestone payments;
- on December 3, 2021, Sanofi acquired the entire share capital of Origimm. The purchase consideration included potential development milestone payments of up to €95 million (see Note D.1.).

Other major agreements entered into by Sanofi in prior years are described below:

- Kymera (2020): agreement to develop and commercialize protein degrader therapies targeting IRAK4 in patients with immune-inflammatory diseases. Under the terms of the agreement, Sanofi has made an upfront payment of $150 million to Kymera, and could pay up to $2.2 billion subject to attainment of specified milestones;
- Roche (2019): to obtain exclusive over-the-counter (OTC) US rights to Tamiflu® for the prevention and treatment of influenza. Under the terms of the agreement, Sanofi is responsible for leading FDA negotiations for the OTC switch; for subsequent exclusive marketing and distribution of Tamiflu® in the US consumer health care market; and for associated scientific engagement. Tamiflu® was previously currently sold in the US for prescription use by Genentech, a member of the Roche Group;
- Regeneron: (i) several amendments to the 2009 Amended and Restated License and Collaboration Agreement on human therapeutic antibodies; (ii) several amendments to the 2015 Immuno-Oncology License and Collaboration Agreement on the development of cemiplimab (REGN2810); and (iii) the 2020 Cross License and Commercialization Agreement for Praluent® (see Note C.1.);
- AnaBios Corporation (2018): partnership agreement to develop and commercialize new treatments for irregular heartbeat, primarily atrial fibrillation;
- SK Chemicals (2018): partnership agreement between Sanofi Pasteur and SK Chemicals under which Sanofi acquired exclusive development and commercialization rights in the United States and Europe for vaccines derived from the cell-based technology developed by SK Chemicals;
- Revolution Medicines (2018): partnership agreement in oncology to jointly develop the principal candidate derived from Revolution Medicines biological research: RMC 4630, an inhibitor of SHP2, a cellular enzyme in the protein tyrosine phosphatase family that plays an important role in multiple forms of cancer;
- Denali Therapeutics Inc. (2018): collaboration agreement on the development of multiple molecules with the potential to treat a range of neurological and systemic inflammatory diseases. The two lead molecules are DNL747 in multiple sclerosis and amyotrophic lateral sclerosis, and DNL758 in systemic inflammatory diseases such as rheumatoid arthritis and psoriasis;
- Immunext (2017): agreement to develop a novel antibody to treat auto-immune diseases such as multiple sclerosis and lupus. Under the agreement, Sanofi acquired an exclusive worldwide license to INX-021, a monoclonal CD40L antibody currently in preclinical development. A second parallel agreement was signed to support clinical trials;
- MedImmune (a division of AstraZeneca) (2017): agreement to develop and commercialize a monoclonal antibody (MEDI8897) for the prevention of Respiratory Syncytial Virus (RSV) associated illness in newborns and infants;
- ImmunoGen (2017): amendment to the license and collaboration agreement signed in 2003. ImmunoGen granted Sanofi a fully paid and exclusive license to develop, manufacture and commercialize the full series of compounds developed by Sanofi using ImmunoGen technology;
- DiCE Molecules (2016): five-year global collaboration to discover potential new therapeutics for up to 12 targets that encompass all disease areas of strategic interest to Sanofi;
- Innate Pharma (2016): collaboration and licensing agreement to apply Innate Pharma's new proprietary technology to the development of innovative bispecific antibody formats engaging natural killer (NK) cells to kill tumor cells through the activating receptor NKp46;

- BioNTech A.G. (2015): exclusive collaboration and license agreement to discover and develop up to five cancer immunotherapies;
- Evotec AG and Apeiron Biologics AG (2015): collaboration and license agreement to discover and develop first-in-class small molecule-based immuno-oncology therapies to treat solid and hematological cancers;
- Eli Lilly and Company (2014): agreement to pursue regulatory approval for non-prescription Cialis® (tadalafil);
- Regulus Therapeutics Inc. (2010): discovery, development and commercialization of novel micro-RNA therapeutics in fibrosis.

Sanofi and its alliance partners have decided to terminate the following agreements (the related commitments are no longer included in Sanofi's off balance sheet disclosures as of December 31, 2021):

- at the end of December 2021, Sanofi and Sangamo Therapeutics, Inc. agreed to end their agreement to research, develop, and commercialize therapeutics for hemoglobinopathies in June 2022, after a transitional phase;
- on September 15, 2021, Sanofi and Lead Pharma decided to end the research collaboration and license agreement for the discovery, development and commercialization of small molecule therapies directed against "ROR gamma t" nuclear hormone receptors to treat auto-immune diseases;
- on April 16, 2021, Sanofi acquired Kiadis, thereby terminating the 2020 license agreement; and on September 14, 2021, Sanofi acquired Translate Bio, thereby terminating the 2018 license agreement as amended in 2020.

Sanofi entered into an agreement with Royalty Pharma in December 2014 relating to development programs under which Royalty Pharma bears a portion of the remaining development costs of the project on a quarterly basis in return for royalties on future sales. This transaction is a co-investment, whereby the partner acquires an interest in the jointly-developed product by providing funding towards the development program. Consequently, the amounts received by Sanofi are recorded as a reduction in development costs, to the extent that the development costs incurred by Sanofi are recognized in profit or loss in accordance with the policies described in Note B.4.1. The products in development under the December 2014 agreement with Royalty Pharma have been launched in the United States and Europe, marking the end of the joint development programs.

On February 27, 2017, Sanofi and Lonza announced a strategic partnership in the form of a joint venture to build and operate a large-scale mammalian cell culture facility for monoclonal antibody production in Visp, Switzerland. An initial investment of approximately €0.3 billion to finance construction of the facility, split 50/50 between the two partners, has now been made in full. In addition, Sanofi could pay Lonza in the region of €0.7 billion over the next fifteen years partly as its share of operating expenses and the cost of producing future batches.

In February 2014, pursuant to the "Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits" (still effective as of December 31, 2021), Sanofi Pasteur and the World Health Organization (WHO) signed a bilateral "Standard Material Transfer Agreement" (SMTA 2). This agreement stipulates that Sanofi Pasteur will, during declared pandemic periods, (i) donate 7.5% of its real-time production of pandemic vaccines against any strain with potential to cause a pandemic, and (ii) reserve a further 7.5% of such production on affordable terms. The agreement cancels and replaces all preceding commitments to donate pandemic vaccines to the WHO.

D.21.2. Off balance sheet commitments relating to financing activities

Credit facilities

Undrawn credit facilities are as follows:

December 31, 2021		Expiry			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
General-purpose credit facilities	8,000	4,000	—	4,000	—

As of December 31, 2021, total credit facilities amounted to €8,000 million (versus €8,000 million as of December 31, 2020 and €8,000 million as of December 31, 2019).

Guarantees

The table below shows the amount of guarantees given and received:

(€ million)	2021	2020	2019
Guarantees given:	**3,794**	**3,291**	**3,103**
• Guarantees provided to banks in connection with credit facilities	1,042	695	1,263
• Other guarantees given	2,752	2,596	1,840
Guarantees received	**(1,149)**	**(964)**	**(703)**

D.21.3. Off balance sheet commitments relating to Sanofi entities and business combinations

On December 21, 2021, Sanofi announced that it had entered into an agreement to acquire Amunix Pharmaceuticals, Inc. for an upfront payment of approximately $1 billion and up to $225 million upon achievement of certain future development milestones.

In addition, commitments received in respect of (i) disposal proceeds receivable under agreements to divest assets (including securities) not yet finalized or (ii) contingent consideration on divestments of operations under past agreements, amounted to a total of €0.8 billion as of December 31, 2021 and €0.6 billion as of December 31, 2020.

Off balance sheet funding commitments to associates and joint ventures are disclosed in Note D.6.

The maximum amount of contingent consideration relating to business combinations is disclosed in Note D.18.

D.22. Legal and arbitral proceedings

Sanofi and its affiliates are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of Sanofi products), competition law and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. Provisions related to legal and arbitral proceedings are recorded in accordance with the principles described in Note B.12.

Most of the issues raised by these claims are highly complex and subject to substantial uncertainties; therefore, the probability of loss and an estimation of damages are difficult to ascertain. Contingent liabilities are cases for which either we are unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding, or a cash outflow is not probable. In either case, a brief description of the nature of the contingent liability is disclosed and, where practicable, an estimate of its financial effect, an indication of the uncertainties relating to the amount and timing of any outflow, and the possibility of any reimbursement are provided in application of paragraph 86 of IAS 37.

In the cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed, we have indicated our losses or the amount of provision accrued that is the estimate of the probable loss.

In a limited number of ongoing cases, while we are able to make a reasonable estimate of the expected loss or range of the possible loss and have accrued a provision for such loss, we believe that publication of this information on a case-by-case basis or by class would seriously prejudice the Company's position in the ongoing legal proceedings or in any related settlement discussions. Accordingly, in those cases, we have disclosed information with respect to the nature of the contingency but have not disclosed our estimate of the range of potential loss, in accordance with paragraph 92 of IAS 37.

These assessments can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Our assessments are based on estimates and assumptions that have been deemed reasonable by management. We believe that the aggregate provisions recorded for the above matters are adequate based upon currently available information. However, given the inherent uncertainties related to these cases and involved in estimating contingent liabilities, we could in the future incur judgments that could have a material adverse effect on our net income in any particular period.

Long term provisions are disclosed in Note D.19. They include:

- provisions for product liability risks, litigation and other amount to €1,374 million in 2021. These provisions are mainly related to product liabilities, government investigations, competition law, regulatory claims, warranties in connection with certain contingent liabilities arising from business divestitures other than environmental matters and other claims;
- provisions for environmental risks and remediation amount to €650 million in 2021, the majority of which are related to contingencies that have arisen from business divestitures.

a) Products

Sanofi Pasteur Hepatitis B Vaccine Product Litigation

Since 1996, more than 180 lawsuits have been filed in various French civil courts against Sanofi Pasteur and/or Sanofi Pasteur MSD S.N.C., the former French subsidiary of Sanofi, and the latter a joint venture company with Merck & Co., Inc. now terminated, for which past ongoing litigation is now managed by the originating party. In such lawsuits, the plaintiffs allege that they suffer from a variety of neurological disorders and autoimmune diseases, including multiple sclerosis and Guillain-Barré syndrome as a result of receiving the hepatitis B vaccine.

In January 2018, the Appeal Court of Bordeaux found a causal link between hepatitis B vaccine and multiple sclerosis. In July 2019, the French Supreme Court *(Cour de cassation)* cancelled the judgment of the Appeal Court of Bordeaux and referred the case back to the Appeal Court of Toulouse. The hearing was held in December 2021 and the ruling is expected in the first quarter of 2022.

As of December 31, 2021, there were 12 ongoing lawsuits related to Sanofi Pasteur hepatitis B vaccine.

Taxotere® Product Litigation in the US

As of December 31, 2021, there were approximately 9,504 plaintiffs in courts across the country, with approximately 823 of those plaintiffs being spouses who have filed loss of consortium claims.

Lawsuits have been filed against affiliates of Sanofi under US state law for personal injuries allegedly sustained in connection with the use of Taxotere®. The actions are held in several jurisdictions, including the federal and/or state courts of Louisiana, New Jersey, California, and Delaware. To date, there have been two bellwether trials as part of a federal multi-district litigation in the Eastern District of Louisiana both resulting in jury verdicts in Sanofi's favor.

It is not possible, at this stage, to reliably assess the outcome of these lawsuits or the potential financial impact on the Company.

Taxotere® – Mississippi Attorney General Litigation in the US

In October 2018, the Attorney General for the State of Mississippi filed a civil action in Hinds County, Mississippi, Chancery Court against various Sanofi Defendants related to Taxotere®. The State asserts one cause of action based on the Mississippi Consumer Protection Act ("MCPA") and seeks a permanent injunction prohibiting Defendants' conduct and civil penalties of up to $10,000 for each violation. In December 2018, Sanofi removed the matter to the US District Court for the Southern District of Mississippi, but the case was subsequently remanded back to State Court in February 2019. Sanofi filed a motion to dismiss the entire action in Hinds County, Mississippi, Chancery Court, which is currently pending.

It is not possible, at this stage, to assess reliably the outcome of this lawsuit or the potential financial impact on the Company.

Zantac® Litigation in the US

In September 2019, the US Food and Drug Administration ("FDA") announced it was investigating the claims of an online pharmacy's Citizen Petition that the medication Zantac® (the brand name for ranitidine) used for stomach heartburn contains or can generate the chemical N-Nitrosodimethylamine ("NDMA"), an alleged human carcinogen. As a precautionary measure, Sanofi initiated a voluntary recall of branded over-the-counter Zantac® in October 2019. Concurrent with FDA's investigation, multiple personal injury lawsuits and class actions alleging that Zantac® causes various cancers and seeking damages for either alleged personal injuries or alleged economic injuries were filed. Most of those cases have been coordinated into a Multi-District Litigation ("MDL") in the Southern District of Florida.

On June 30 and July 8, 2021, the Federal MDL Court entered orders granting in part and denying in part Defendants' motions to dismiss various aspects of Plaintiffs' amended complaints. The rulings narrowed the scope of plaintiffs' complaints and saw the dismissal of all retailers and generic manufacturers from the MDL, leaving branded manufacturers GSK, Pfizer, Boehringer Ingelheim, and Sanofi as the defendants.

As of December 31, 2021, there were 1,828 filed personal injury cases in the MDL comprising 1,927 personal injury plaintiffs alleging claims against Sanofi.

Other cases are pending in various state courts. These state court cases still include numerous retail and generics manufacturing defendants in addition to branded manufacturers.

In addition, in November 2019, Sanofi received a Civil Investigative Demand ("CID") related to this issue from the Arizona Attorney General.

In June 2020, the New Mexico Attorney General filed a complaint against Sanofi, the previous marketing authorization holders for branded Zantac®, a dozen generic manufacturers, and several retailers. The complaint brings claims for alleged violations of the New Mexico Unfair Practices Act, violations of the New Mexico False Advertising Act, violations of the New Mexico Public Nuisance Statute, common law public nuisance, and negligence.

In June 2020, Sanofi received a notice from the US Department of Justice Civil Division and US Attorney's Office for the Eastern District of Pennsylvania of an investigation into allegations that pharmaceutical manufacturers violated the False Claims Act, 31 U.S.C. § 3729, in relation to the drug Zantac® and ranitidine hydrochloride through alleged failure to disclose to the federal government information about the potential presence of NDMA. The notice requests information and documents from Sanofi including applications and communications with FDA.

In November 2020, the Mayor and City Council of Baltimore filed a complaint against Sanofi, the previous marketing authorization holders for branded Zantac®, generic manufacturers, and several retailers. The complaint alleges violations of the Maryland Consumer Protection statute, public nuisance, and negligence.

In January 2021, Sanofi was served with the Center for Environmental Health's Second Amended Complaint alleging Proposition 65 violations. The case, which also names generic manufacturers and retailers, is pending in California Superior Court in Alameda County.

Overall between State and federal filings, there are currently 1,971 product liability "complaints" filed. These complaints encompass 3,086 individual product liability "plaintiffs" who have all filed against Sanofi. Additional cases may be filed.

It is not possible, at this stage, to assess reliably the outcome of these lawsuits or the potential financial impact on Sanofi.

Zantac® Litigation in Canada

Between 2019 and 2021, 7 proposed class actions naming notably Sanofi Consumer Health Inc., Sanofi-Aventis Canada Inc., Chattem (Canada) Inc., Sanofi and Sanofi Pasteur Limited as Defendants, relating to ranitidine were filed in various Canadian States court on behalf of all Canadian provinces alleging they suffered personal injury, including cancer, from the ingestion of ranitidine and are seeking general special, statutory, punitive and aggravated damages in an unspecified amount as well as disgorgement of profits. Additionally, some plaintiffs seek restitution for unjust enrichment in an amount equivalent to the purchase price of Zantac® and subrogated damages on behalf of provincial health insurers for health care costs related to ranitidine use. These actions are pending before the courts of Alberta, British Columbia, Quebec and Ontario.

It is not possible, at this stage, to assess reliably the outcome of these lawsuits or the potential financial impact on Sanofi.

Depakine® Product Litigation in France

Civil proceedings

As of December 31, 2021, 75 families brought a civil claim involving 127 people exposed *in utero* to sodium valproate against a French affiliate of Sanofi seeking indemnification under French law for personal injuries allegedly suffered by children in connection with the use of sodium valproate by their mothers during pregnancy to treat their epilepsy (Depakine®). These actions are held in several jurisdictions in France.

Twenty-six lawsuits are proceedings on the merits, the most advanced was tried at the French Supreme Court level which issued in November 2019 a ruling quashing partially the November 2017 Orléans Appeal Court decision against Sanofi ordering payment of approximately €2 million to the plaintiff and €1 million to the CPAM *(Caisse Primaire d'Assurance Maladie)*. The Supreme Court decided to send the case before another Appeal Court of Paris to rule on Sanofi's argument on the exoneration cause relating "to compliance of the product with mandatory regulations", as well as on the question of defectiveness of the product and the evaluation of the injuries. There is no date set for the hearing of the case yet.

Several first instance rulings on the merits are expected to occur in Q2-Q3 2022 from the Judicial Tribunal of Nanterre.

In the class action lawsuit filed in May 2017 by the APESAC *(Association des Parents d'Enfants souffrant du Syndrome de l'Anti-Convulsivant)* against the French affiliate, the Judicial Tribunal of Paris ruled on January 5, 2022 that a class is admissible, retaining Sanofi's liability (i) for breach of its obligation of vigilance and of its duty to inform as of 1984 until January 2006 for the risk of malformation and as of 2001 until January 2006 for the risks of neurodevelopmental disorders (NDD) and (ii) for commercializing a defective product by lack of information on the patient leaflet from 1998 to 2006 for malformation and from 2001 to 2006 for NDD. This decision is based on the conclusions of a criminal expert report within the frame of ongoing criminal proceeding, for which, however, on December 15, 2021, the *Chambre de l'Instruction* of the Appeal Court of Paris had ordered a counter-expertise as per Sanofi's request (see below). Sanofi and its insurers, also parties to the lawsuit, will file an appeal against the decision from the Judicial Tribunal of Paris on the class action. Consequently, execution of the decision is suspended until definitive decision is rendered.

On July 21, 2021, a Judicial Tribunal in France dismissed a claim for damages brought against Sanofi regarding a child born in 1995. The Judicial Tribunal considered that the risk of occurrence of NDD in children born to mother exposed to sodium valproate during pregnancy was not demonstrated by the state of scientific knowledge at the time of her pregnancy. This decision is now pending before the Appeal Court of Paris.

In July 2020, a collective redress against the French affiliate was filed by 63 families, seeking indemnification for a prejudice of anxiety. There is no date set for the hearing of the case yet.

Criminal investigation

A criminal investigation was initiated in May 2015 before the Paris Civil Court. In January 2020, the French affiliate of Sanofi was indicted for aggravated deception and involuntary injuries and in July 2020 for involuntary manslaughter. In July 2020, a judicial supervision of the affiliate was ordered, together with the implementation of financial guarantees. In November 2020, the Health Authority (ANSM) was similarly indicted for involuntary injuries and involuntary manslaughters. Sanofi's motions for nullity of its indictment have been rejected by the *Chambre de l'Instruction* of the Appeal Court of Paris on October 13, 2021. However, on December 15, 2021, the *Chambre de l'Instruction* of the Appeal Court of Paris ordered a counter-expertise considering that Sanofi's request for a counter expertise was justified, in the interest of good administration of justice, right to an equitable trial and rights of defense.

Public compensation scheme

The French government has, through the 2017 Finance Law adopted on December 29, 2016, set up a public compensation scheme to indemnify patients for damages suffered in connection with the prescription of sodium valproate and its derivatives. The scheme entered into force in July 2017 and was further amended through the 2020 Finance Law, with notably the introduction of presumptions of default for lack of information of the mother since 1982 for malformations and since 1984 for NDD. The scheme was amended again through the 2021 Finance Law in order to increase the maximum premium applicable in case of refusal to make an offer (or insufficient offer) which would be deemed unjustified by a court ruling.

The committee of the compensation scheme has issued several final opinions holding the French affiliate liable for damages either in full or in part along with the French State. The French affiliate disagreed with the committee's conclusions and has accordingly not offered indemnification to the claimants who have received compensation from the ONIAM *(Office National d'Indemnisation des Accidents Médicaux)*. The ONIAM is now seeking reimbursement from Sanofi who has filed legal actions to oppose ONIAM's payment orders.

Sanofi has also been notified of 53 exposed persons who have filed a request for indemnification before the public compensation scheme and who are also claimants against Sanofi in judicial proceedings.

Administrative Actions

In July 2020 and March 2021, a court had recognized the responsibility of the French State in 4 administrative proceedings initiated by families against the State. In March 2021, the Administrative Court did not retain any lack of information of the mother regarding the risk of neurodevelopmental disorders for pregnancies occurring in 1998 and in 2001, based on the state of scientific knowledge at the time. However, regarding the risk of malformations, liabilities were retained against the State, the healthcare professionals and Sanofi, notably for discrepancy between the SmPC (Summary of the Product Characteristics) and the patient leaflet. Given that the French affiliate was not a party to these administrative proceedings, its arguments (i.e. notably several requests from the French affiliate to the Health Authorities to reinforce warnings to healthcare professionals and patients in relation to Depakine®) were not considered. Sanofi has filed requests for voluntary intervention in these proceedings to present its arguments before the Administrative Court of Appeal.

It is not possible, at this stage, to assess reliably the outcome of these cases or the potential financial impact on the Company.

Depakine® Product Litigation in other EU countries

In Switzerland, 10 families have filed a civil claim for damages concerning 15 people exposed in utero. Some of them also involve the claimants' physicians.

In Spain, there are 2 trials ongoing relating to 5 children.

In Belgium, there are 2 civil proceedings (currently on hold) and a criminal complaint against X and against Sanofi.

In Germany, there is one civil lawsuit before the Berlin Regional Court, relating to one child exposed *in utero* to valproate taken by the mother during pregnancy for bipolar disorder.

Dengvaxia® (Philippines)

Since early 2018 up to present date, several claims were filed in the Philippines by parents of deceased children whose deaths were allegedly due to vaccination with Dengvaxia®. Early March 2019 and 2020, the Philippine Department of Justice (DOJ) prosecution panel announced it had found probable cause to indict several Sanofi employees/former employees and former Government officials for "reckless imprudence" resulting in homicides. Since then, several criminal actions have been filed in court as a result of this finding. Motions for Reconsideration (MR) have been filed by Sanofi Pasteur Inc. (Philippines) and were dismissed for all respondents except for one Sanofi employee. Petitions for Review to the DOJ Secretary have been filed, appealing the dismissed MR and the said petitions remain pending. Meanwhile, the first cases that were filed in March 2019 have progressed in the lower court. The majority of the respondents have challenged the jurisdiction of the lower court where the first 8 cases had been assigned and this issue is now filed with the Supreme Court. There are several claims that remain pending with the DOJ, awaiting probable cause resolution.

b) Patents

Ramipril Canada Patent Litigation

Sanofi was involved in a number of legal proceedings involving companies which market generic Altace® (ramipril) in Canada. In 2004, Sanofi unsuccessfully brought Notice of Compliance proceedings (NOC proceedings) at the end of which eight manufacturers obtained marketing authorizations from the Canadian Minister of Health for generic versions of ramipril in Canada. Sanofi filed unsuccessful patent infringement actions against all those companies and ultimately Sanofi was liable for damages under Section 8. Sanofi made payment in complete satisfaction of those awards.

In June 2011, while the Section 8 damages action was proceeding in Federal Court, Apotex commenced an action in the Ontario Superior Court of Justice asserting damages under the Ontario Statute of Monopolies, the UK Statute of Monopolies, and the Trade-marks Act (the "Ontario Action"). The Ontario Action was stayed pending exhaustion of appeals in the Section 8 damages action and, despite having received full compensation in the Section 8 action, was reinitiated by Apotex after the conclusion of the appeals.

At the request of the parties, in June 2021, the Court ordered that the action be stayed in view of the lower court's decision in March in the Apotex vs. Lilly case. In the Lilly case, the Court dismissed Apotex's Statute of Monopolies claim by way of summary judgment. If upheld on appeal, this decision may end Apotex's claim against Sanofi, also based on the Statute of Monopolies. It is anticipated that the appeals process, through finality will take approximately 24 months.

Praluent® (alirocumab)-related Amgen Patent Litigation in the US

In 2014, Amgen filed four separate complaints against Sanofi and Regeneron in the US District Court for the District of Delaware ("District Court") asserting patent infringement relating to Sanofi and Regeneron's Praluent® product. Together these complaints alleged that Praluent® infringed seven patents for antibodies targeting PCSK9 and sought injunctive relief and unspecified damages.

In 2019, Sanofi and Regeneron successfully invalidated all five asserted patent claims in the District Court. Amgen appealed to the Federal Circuit.

In February 2021, the Federal Circuit affirmed the District Court's ruling invalidating the Amgen asserted patent claims. In June 2021, the Federal Circuit denied Amgen's petition for rehearing. In November 2021, Amgen filed a petition with the US Supreme Court, asking it to overturn the Federal Circuit decision. In January 2022, the US Supreme Court requested a response from Sanofi and Regeneron to Amgen's petition.

Dupixent® (dupilumab)-related Amgen Patent Opposition and Revocation in Europe

Immunex Corporation, an Amgen affiliate, is the registered proprietor of European Patent EP2292665. The claims of this patent relate to, among other things, human monoclonal antibodies that are capable of inhibiting IL-4 induced biological activity and which compete with one of four reference antibodies for binding to a cell that expresses human IL-4R. In April 2016, Sanofi and Regeneron each filed an opposition in the European Patent Office (EPO) against EP2292665, seeking its revocation on the basis that, inter alia, the claims are invalid for prohibited "added matter", lack of novelty, lack of inventive step and lack of sufficient disclosure. In September 2016, Sanofi also filed a civil action in the UK High Court (Chancery Division/Patents Court) seeking revocation of the UK designation of EP2292665 on similar grounds. In January 2017, at the joint request of Sanofi and Immunex, the UK High Court ordered that the revocation action be stayed pending the final determination of the pending EPO opposition proceedings.

The EPO rendered its decision in November 2017 and revoked the patent in its entirety. In early 2018, Immunex appealed the decision of the EPO.

In September 2017, Sanofi and Regeneron filed oppositions in the EPO against Amgen's European Patent EP2990420, which is a divisional of the EP2292665 Patent discussed above. The issues in this opposition were similar to those made in the oppositions against EP2292665.

In February 2019, the EPO revoked the patent EP2990420 in its entirety, finding the claims invalid for lack of sufficiency. Immunex filed a notice of appeal in May 2019.

Oral hearings by the Technical Board of Appeals have been scheduled for March 2022.

Dupixent® (dupilumab)-related Amgen Inter Partes Reviews and Patent Litigation in the US

Amgen filed a Petition for Writ of Certiorari to the US Supreme Court challenging the Federal Circuit's affirmance that all claims of US Patent No. 8,679,487 are invalid, which petition the Court denied in June 2021. Amgen's '487 patent is invalid with no further possibility of appeal. In August 2021, the associated district court case was dismissed bringing these matters to a close.

Jevtana® (cabazitaxel)-related patent litigation in the US

Jevtana® is currently covered by four Orange Book listed patents US 7,241,907, US 8,927,592, US 10,583,110 and US 10,716,777. In May to July 2020, Sanofi filed patent infringement suits under Hatch-Waxman against 12 generic filers asserting the '110 patent and the '777 patent in the US District Court for the District of Delaware. The '592 patent was added to the suits after its amended claims issued

in August 2021. Sanofi has reached settlement agreements with some of the defendants and the suit against the remaining defendants is ongoing. In January 2021, the District Court issued a claim construction decision in favor of the defendants. In September 2021, the remaining defendants Apotex and Sandoz filed a motion to dismiss the infringement suit. No trial date has been scheduled and the remaining defendants have agreed not to launch any generic cabazitaxel product until the earlier of a district court decision in favor of the defendants or four months after the completion of the post-trial briefing. In January 2022, Sanofi filed a patent infringement suit under Hatch-Waxman against Aurobindo Pharma and Eugia Pharma in the US District Court for the District of Delaware asserting the '592, '110 and '777 patents.

Plavix® Litigation (Commonwealth) in Australia

In August 2007, GenRX (a subsidiary of Apotex) obtained registration of a generic clopidogrel bisulfate product on the Australian Register of Therapeutic Goods. At the same time, GenRX filed a patent invalidation action with the Federal Court of Australia, seeking revocation of Sanofi's Australian enantiomer patent claiming clopidogrel salts (a "nullity action"). In September 2007, Sanofi obtained a preliminary injunction from the Federal Court preventing commercial launch of this generic clopidogrel bisulfate product until judgment on the substantive issues of patent validity and infringement.

In August 2008, the Australian Federal Court confirmed that the claim in Sanofi's Australian enantiomer patent directed to clopidogrel bisulfate (the salt form in Plavix®) was valid and the patent infringed. On appeal, the Full Federal Court of Australia held in September 2009 that all claims in the patent are invalid. Sanofi's appeal to the Australia High Court was denied in March 2010.

In April 2013, the Australian Department of Health and Ageing ("Commonwealth") filed an application before the Federal Court of Australia seeking payment of damages from Sanofi related to the Apotex preliminary injunction of up to AUD449 million (€287 million as of December 31, 2021), plus interest.

Sanofi and BMS settled the patent litigation with Apotex in November 2014. In April 2020, the Commonwealth's claim was dismissed. In May 2020, the Commonwealth filed a Notice of Appeal to the Full Court of the Federal Court. On appeal, the Commonwealth reduced its claim to a range of AUD223.3 million (€142.7 million) to AUD280.2 million (€179.1 million) which, inclusive of interest to December 31, 2021, ranges from AUD333.4 million (€213.1 million) to AUD453.6 million (€289.9 million) depending on whether interest accrues from the date the Commonwealth claims the Apotex products would have been listed on the Government reimbursement scheme in the absence of the injunction (i.e. April 1, 2008) or the date the Commonwealth filed its claim (i.e. April 1, 2013). Appeal hearing took place in February 2021 before the Full Court of the Federal Court. The ruling is expected in 2022.

c) Other litigation

Aubagio® (teriflunomide)-related litigation in Europe

In October 2020, Mylan Ireland Ltd ('Mylan') brought an action before the General Court of the European Union requesting the annulment of the August 18, 2020 decision of the European Medicines Agency ("EMA") refusing to validate Mylan's marketing authorization application for a generic version of Aubagio® (teriflunomide). Sanofi has intervened in this court case between Mylan and the EMA in order to defend Aubagio's regulatory exclusivity. The proceedings before the General Court are still ongoing.

Plavix® (clopidogrel) – Attorney General Action in Hawaii

In March 2014, the Hawaii Attorney General (AG) filed a complaint that sets forth allegations related to the sale and marketing of and variability of response to Plavix®. The Hawaii AG specifically alleged that Plavix® had a diminished effect in patients of certain genetic backgrounds and that Sanofi and BMS had failed to make an earlier disclosure of this information.

In February 2021, the Court issued its decision, imposing penalties in the total amount of $834,012,000 against both Sanofi and Bristol Myers Squibb (BMS), with $417,006,000 being apportioned to each company. In June 2021, Sanofi and BMS appealed this judgment. To the extent this judgment or possibly a reduced judgment remains after the appeal, the judgment would be split evenly with BMS.

Plavix® (clopidogrel) - Attorney General Action in New Mexico

In September 2016, the New Mexico Attorney General (AG) filed a complaint, claiming that Sanofi and Bristol Meyers Squibb (BMS) engaged in unfair and deceptive practices related to the marketing and labelling of Plavix®. The New Mexico AG specifically alleged that Plavix® had a diminished effect in patients of certain genetic backgrounds and that the Companies failed to make an earlier disclosure of this information. Discovery is completed.

Plavix® (clopidogrel)-related litigation in France

In France, in the claim concerning allegations that Sanofi's communication and promotional practices inhibited the entry on the market of generics of clopidogrel (the active ingredient of Plavix®), the French Antitrust Authority issued its decision on May 14, 2013, imposing on Sanofi a fine of €40.6 million. In December 2014, the Paris Court of Appeals rejected Sanofi's appeal and confirmed in totality the decision. As a consequence of the May 2013 ruling, claims were filed by Sandoz and by Teva in 2014 before the Commercial Court of Paris for compensation of their alleged damages: loss of margin and other ancillary damages (legal fees to external counsel, image and reputation). In June and November 2016 respectively, settlement agreements were entered into with Sandoz and Teva. Consequently, they subsequently withdrew their civil claims, jointly and severally. On October 18, 2016, the Supreme Court confirmed the Court of Appeals' decision. Therefore, the Court of Appeals' decision became definitive. In September 2017, Sanofi and its French affiliate received a summons before the Paris Commercial Court from the *French Caisse Nationale d'Assurance Maladie – CNAM* (French Social Security) claiming €115.8 million for their alleged damages. On October 1, 2019, the Paris Commercial Court dismissed the CNAM's action as time barred. In November 2019, the CNAM lodged an appeal. The CNAM appeal hearing took place in October 2021 and a ruling is expected in February 2022.

340B Drug Pricing Program in the United States

Sanofi is currently involved in several matters relating to the 340B program in the US (a federal program that requires drug manufacturers to supply certain products to certain "covered entities" at reduced prices). In 2021, Sanofi filed a lawsuit against the Department of Health and Human Services ("HHS"), the Health Resources and Services Administration ("HRSA"), and certain of their administrators in

the US District Court for the District of New Jersey challenging (i) HHS's December 2020 Advisory Opinion (the "AO") stating that drug manufacturers are legally obligated to deliver discounts under the 340B program to an unlimited number of contract pharmacies; (ii) HHS's December 2020 Administrative Dispute Resolution ("ADR") Rule; and (iii) HRSA's May 2021 letter to Sanofi concluding that Sanofi's 340B integrity initiative (under which Sanofi collects limited, de-identified, claims data on 340B-priced drugs dispensed by contract pharmacies) violates section 340B and that Sanofi has therefore "overcharged" certain covered entities. The court issued its opinion on November 5, 2021, upholding HRSA's conclusion in the May 2021 letter, but did not impose any fines, penalties or refund obligations against Sanofi for any "overcharges". The court also rejected Sanofi's challenge to the ADR Rule and dismissed its challenge to the AO as moot. Sanofi has appealed the court's decision to the Third Circuit Court of Appeals and the government has filed a cross-appeal.

Sanofi is a defendant in an ADR proceeding before HRSA, filed in January 2021, by the National Association of Community Health Centers ("NACHC"), on behalf of a number of covered entities, seeking to require Sanofi and another manufacturer to supply contract pharmacies with 340B discounts without conditions.

In September 2021, HRSA referred Sanofi (as well as other manufacturers) to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule.

In February 2021, the Vermont Attorney General issued a Civil Investigative Subpoena seeking certain information about Sanofi's participation in the 340B Drug Pricing Program. Sanofi continues to cooperate with this investigation.

In addition, in July 2021, Mosaic Health Inc. and Central Virginia Health Services (covered entities) filed a nationwide antitrust class action complaint against Sanofi and three other manufacturers in the United States District Court for the Western District of New York. Plaintiffs allege that Sanofi and the other defendants conspired to eliminate favorable 340B pricing, particularly with respect to diabetes therapies. Defendants have moved to dismiss the complaint.

d) Contingencies arising from certain business divestitures

Sanofi and its subsidiaries, Hoechst and Aventis Agriculture, divested a variety of mostly chemical, including agro-chemical, businesses as well as certain health product businesses. As a result of these divestitures, the Company is subject to a number of ongoing contractual and legal obligations regarding the state of the sold businesses, their assets, and their liabilities.

Aventis CropScience Retained Liabilities

The sale by Aventis Agriculture S.A. and Hoechst GmbH (both legacy companies of Sanofi) of their aggregate 76% participation in Aventis CropScience Holding (ACS) to Bayer and Bayer CropScience AG (BCS), the wholly owned subsidiary of Bayer which holds the ACS shares, was effective on June 3, 2002. The Stock Purchase Agreement (SPA) dated October 2, 2001, contained customary representations and warranties with respect to the sold business, as well as a number of indemnifications subject to limitation periods and caps, in particular with respect to environmental liabilities for which some outstanding claims from Bayer remain unresolved.

Infraserv Hoechst Retained Liabilities

By the Asset Contribution Agreement dated December 19/20, 1996, as amended in 1997, Hoechst contributed all lands, buildings, and related assets of the Hoechst site at Frankfurt Hoechst to Infraserv GmbH & Co. Hoechst KG. Infraserv Hoechst undertook to indemnify Hoechst against environmental liabilities at the Hoechst site and with respect to certain landfills. As consideration for the indemnification undertaking, Hoechst transferred to Infraserv Hoechst approximately €57 million to fund reserves. In 1997, Hoechst also agreed it would reimburse current and future Infraserv Hoechst environmental expenses up to €143 million. As a former operator of the land and as a former user of the landfills, Hoechst may ultimately be liable for costs of remedial action in excess of this amount.

Boehringer Ingelheim (BI) Retained Liabilities

Sanofi and Boehringer Ingelheim (BI) are involved in an ICC (International Chamber of Commerce) arbitration regarding their respective indemnification obligations for liabilities connected to ongoing US court proceedings regarding Zantac® manufactured by BI. The dispute arises from indemnification obligations agreed between Sanofi and BI as part of the swap of Sanofi's Animal Health (AH) business for BI's Consumer Health Care (CHC) business in January 2017 and under a Global Settlement Agreement concluded in September 2019 regarding notably the offset of respective AH and CHC claims notified under the SPAs.

In February 2020, BI initiated an arbitration against Sanofi seeking indemnification for losses it could incur as a result of the Zantac® litigation in the US. Sanofi is disputing BI's claim for indemnification and has asserted several counterclaims under relevant agreements, including a counterclaim for indemnification of losses Sanofi and its affiliates have incurred and may incur in connection with the same US court proceedings involving Zantac®. The arbitration is ongoing.

D.23. Provisions for discounts, rebates and sales returns

Adjustments between gross sales and net sales, as described in Note B.13., are recognized either as provisions or as reductions in accounts receivable, depending on their nature.

The table below shows movements in these items:

(€ million)		Government and State programs[a]	Managed care and GPO programs[b]	Chargeback incentives	Rebates and discounts	Sales returns	Other deductions	Total
Balance at January 1, 2019		**2,148**	**674**	**294**	**1,140**	**546**	**13**	**4,815**
Provision related to current period sales		5,542	2,563	4,649	5,888	554	96	19,292
Net change in provision related to prior period sales		(27)	—	(1)	(6)	(27)	14	(47)
Payments made		(5,529)	(2,528)	(4,637)	(5,719)	(465)	(72)	(18,950)
Currency translation differences		44	17	7	27	13	—	108
Balance at December 31, 2019	[c]	**2,178**	**726**	**312**	**1,330**	**621**	**51**	**5,218**
Provision related to current period sales		5,970	2,752	4,633	6,221	628	110	20,314
Net change in provision related to prior period sales		(54)	—	—	(113)	(34)	—	(201)
Payments made		(5,552)	(2,556)	(4,604)	(5,838)	(512)	(112)	(19,174)
Currency translation differences		(35)	(14)	(8)	(43)	(15)	(3)	(118)
Balance at December 31, 2020	[c]	**2,507**	**908**	**333**	**1,557**	**688**	**46**	**6,039**
Changes in scope of consolidation		3	—	—	(2)	1	—	2
Provision related to current period sales		5,855	3,037	3,813	6,330	582	97	19,714
Net change in provision related to prior period sales		(136)	(3)	(4)	(152)	56	(3)	(242)
Payments made		(5,561)	(2,979)	(3,828)	(6,291)	(697)	(105)	(19,461)
Currency translation differences		(72)	(32)	(11)	(17)	(20)	(1)	(153)
Balance at December 31, 2021	[c]	**2,596**	**931**	**303**	**1,425**	**610**	**34**	**5,899**

(a) Primarily US government programs: Medicaid (€1,244 million in 2021, €1,015 million in 2020, €1,017 million in 2019) and Medicare (€941 million in 2021, €726 million in 2019 and €810 million in 2019).

(b) Mainly rebates and other price reductions granted to healthcare authorities in the United States (including Managed Care: €896 million in 2021, €692 million in 2020 and €649 million in 2019).

(c) Provisions related to US net sales amounted to €4,057 million as of December 31, 2021, €3,982 million as of December 31, 2020 and €3,585 million as of December 31, 2019.

D.24. Personnel costs

Total personnel costs (other than termination benefits, presented in Note D.27.) include the following items:

(€ million)	2021	2020	2019
Salaries	6,625	6,508	6,590
Social security charges (including defined-contribution pension plans)	1,929	1,874	1,949
Stock options and other share-based payment expense	244	274	252
Defined-benefit plans[a]	273	162	168
Other employee benefits	269	261	229
Total	**9,340**	**9,079**	**9,188**

(a) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (see Note A.2.1.).

The total number of registered employees was 95,442 as of December 31, 2021, compared with 99,412 as of December 31, 2020 and 100,409 as of December 31, 2019.

D.25. Other operating income

Other operating income totaled €859 million in 2021, versus €697 million in 2020 and €783 million in 2019.

Other operating income includes (i) gains from asset divestments, amounting to €418 million in 2021 (versus €307 million in 2020 and €296 million in 2019); (ii) income from Sanofi's pharmaceutical partners, amounting to €245 million in 2021 (including €195 million from Regeneron, see Note D.26. below), compared with €199 million in 2020 and €103 million in 2019. This line item also includes (i) for 2021, a payment of €119 million from Daiichi Sankyo relating to the termination of a vaccines collaboration agreement in Japan; and (ii) for 2019, the favorable impact of top-up pension plan amendments following the application of the Pacte law in France.

D.26. Other operating expenses

Other operating expenses totaled €1,805 million in 2021, compared with €1,415 million in 2020 and €1,207 million in 2019.

For 2021, this line item includes €1,568 million of expenses relating to the alliance with Regeneron (see Note C.1.), versus €1,090 million for 2020 and €715 million in 2019 (as shown in the table below):

(€ million)	2021	2020	2019
Income & expense related to sharing of (profits)/losses under the Monoclonal Antibody Alliance	(1,253)	(727)	(253)
Additional share of profit paid by Regeneron towards development costs	127	75	21
Reimbursement to Regeneron of selling expenses incurred	(303)	(349)	(449)
Total - Monoclonal Antibody Alliance	**(1,429)**	**(1,001)**	**(681)**
Immuno-Oncology Alliance	**68**	**89**	**62**
Other (mainly Zaltrap®)	**(12)**	**(14)**	**(14)**
Other operating income/(expenses), net related to the Regeneron Alliance	**(1,373)**	**(926)**	**(633)**
*of which amount presented in **Other operating income** (Note D.25.)*	*195*	*164*	*82*

Charges to provisions for litigation and environmental risks are also recorded within this line item.

D.27. Restructuring costs and similar items

Restructuring costs and similar items amounted to €820 million in 2021, €1,089 million in 2020 and €1,088 million in 2019, and were comprised of the following items:

(€ million)	2021	2020 [(a)]	2019 [(a)]
Employee-related expenses	193	697	795
Charges, gains or losses on assets[(b)]	110	149	106
Compensation for early termination of contracts (other than contracts of employment)	34	40	49
Decontamination costs	—	(2)	27
Transformation programs costs	463	191	131
Others	20	14	(20)
Total	**820**	**1,089**	**1,088**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

(b) This line consists of impairment losses and accelerated depreciation charges related to site closures (including leased sites), and gains or losses on divestments of assets arising from reorganization decisions made by Sanofi.

In 2021, the costs of Sanofi's transformation program (as defined in Note B.19.) were related mainly to the creation of the new standalone Consumer Healthcare entity and of EUROAPI (the future European market leader in active pharmaceutical ingredients), and to the implementation of Sanofi's new digital strategy.

In 2020, employee-related expenses amounted to €697 million, and consisted of termination benefits further to the announcement of plans to adapt Sanofi's organization (primarily in Europe) in line with the new "Play to Win" strategy announced in December 2019.

In 2019, restructuring costs were mainly comprised of termination benefits of €795 million (primarily in Europe, the United States and Asia), plus asset write-downs and accelerated depreciation charges of €106 million.

D.28. Other gains and losses, and litigation

Other gains and losses, and litigation for 2021 comprise a charge of €5 million.

For 2020, this line item comprises a net gain of €136 million, mainly relating to the sale of Seprafilm®.

For 2019, this line item comprises a net gain of €327 million, mainly relating to a gain on settlement of litigation.

D.29. Financial expenses and income

An analysis of ***Financial expenses*** and ***Financial income*** is set forth below:

(€ million)	2021	2020 [(d)]	2019 [(d)]
Cost of debt[(a)]	(313)	(328)	(318)
Interest income[(b)]	54	103	146
Cost of net debt	**(259)**	**(225)**	**(172)**
Non-operating foreign exchange gains/(losses)	2	(6)	1
Unwinding of discounting of provisions[(c)]	(11)	(11)	(25)
Net interest cost related to employee benefits	(44)	(57)	(83)
Gains/(losses) on disposals of financial assets	3	6	—
Net interest expense on lease liabilities	(35)	(38)	(39)
Other	16	(4)	19
Net financial income/(expenses)	**(328)**	**(335)**	**(299)**
comprising: Financial expenses	**(368)**	**(388)**	**(440)**
Financial income	**40**	**53**	**141**

(a) Includes net gains on interest rate and currency derivatives used to manage debt: €14 million in 2021, €93 million in 2020 and €187 million in 2019.
(b) Includes net gains on interest rate and currency derivatives used to manage cash and cash equivalents: €51 million in 2021, €66 million in 2020 and €55 million in 2019.
(c) Primarily on provisions for environmental risks, restructuring provisions, and provisions for product-related risks (see Note D.19.).
(d) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (see Note A.2.1.).

In 2021, 2020 and 2019, the impact of the ineffective portion of hedging relationships was not material.

D.30. Income tax expense

Sanofi has elected for tax consolidations in a number of countries, principally France, Germany, the United Kingdom and the United States.

The table below shows the allocation of income tax expense between current and deferred taxes:

(€ million)	2021	2020 [(a)]	2019 [(a)]
Current taxes	(1,908)	(1,913)	(1,892)
Deferred taxes	350	106	1,771
Total	**(1,558)**	**(1,807)**	**(121)**
Income before tax and investments accounted for using the equity method	**7,798**	**13,778**	**2,752**

(a) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

The difference between the effective tax rate and the standard corporate income tax rate applicable in France is explained as follows:

(as a percentage)	2021	2020	2019
Standard tax rate applicable in France	28.4	32.0	34.4
Difference between the standard French tax rate and the rates applicable to Sanofi[(a)]	(9.5)	(18.2)	(23.2)
Revisions to tax exposures and settlements of tax disputes	1.0	0.5	4.9
Impact of past acquisitions and divestitures	—	—	(6.4)
Fair value remeasurement of contingent consideration[(b)]	—	—	(2.7)
Other items[(c)]	0.1	(1.2)	(2.6)
Effective tax rate	**20.0**	**13.1**	**4.4**

(a) The difference between the French tax rate and tax rates applicable to foreign subsidiaries reflects the fact that Sanofi has operations in many countries, most of which have lower tax rates than France. For 2020, this line includes the difference between the standard French tax rate and the tax rate applicable to the gain on divestment of Regeneron shares.
(b) For 2019, this line includes impacts related to the MSD contingent consideration and to the CVRs issued in connection with the acquisition of Genzyme.
(c) In determining the amount of the deferred tax liability for 2021, 2020 and 2019, Sanofi took into account changes in the ownership structure of certain subsidiaries.

For the periods presented, the amount of deferred tax assets recognized in profit or loss that were initially subject to impairment losses at the time of a business combination is immaterial.

D.31. Share of profit/loss from investments accounted for using the equity method

The line item ***Share of profit/(loss) from investments accounted for using the equity method*** comprises:

(€ million)	2021	2020	2019
Regeneron[(a)]	—	343	245
BMS co-promotion entities[(b)]	—	1	5
Other investments accounted for using the equity method	39	15	5
Total	**39**	**359**	**255**

(a) Following the transaction of May 29, 2020 as described in Note D.2., which resulted in the divestment of 22.8 million Regeneron shares, Sanofi no longer exercises significant influence over Regeneron. The 2020 figure presented represents Sanofi's equity-accounted share of Regeneron's net profits up to and including that date.

(b) On February 28, 2020, Sanofi acquired from Bristol-Myers Squibb the remaining 50.1% equity interest not yet held by Sanofi in the three partnerships that organize the commercialization of Plavix® in the United States and Puerto Rico, for a total consideration of $12 million. This acquisition was accounted for in accordance with IFRS 3 (Business Combinations).

D.32. Net income attributable to non-controlling interests

The table below shows ***Net income attributable to non-controlling interests*** for the reporting periods presented:

(€ million)	2021	2020	2019
Share of net income attributable to other non-controlling interests	56	36	31
Total	**56**	**36**	**31**

D.33. Related party transactions

The principal related parties are companies over which Sanofi has control or significant influence, joint ventures, key management personnel, and principal shareholders.

Sanofi has not entered into any material transactions with any key management personnel. Financial relations with Sanofi's principal shareholders fall within the ordinary course of business and were immaterial in the years ended December 31, 2021, 2020 and 2019.

Note F.1. lists the principal companies controlled by Sanofi; those companies are fully consolidated, as described in Note B.1. Transactions between those companies, and between the parent company and its subsidiaries, are eliminated when preparing the consolidated financial statements.

Transactions with companies over which Sanofi has significant influence, and with joint ventures, are presented in Note D.6.

Key management personnel include corporate officers and the members of the Executive Committee (an average of 11 members in 2021, 11 members in 2020 and 15 members in 2019).

The table below shows, by type, the compensation paid to key management personnel:

(€ million)	2021	2020 [(a)]	2019 [(a)]
Short-term benefits[(b)]	33	36	31
Post-employment benefits[(c)]	2	3	(4)
Share-based payment	20	18	30
Total recognized in profit or loss	**55**	**57**	**57**

(a) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (see Note A.2.1.).

(b) Compensation, employer's social security contributions, directors' attendance fees, and any termination benefits (net of reversals of termination benefit obligations).

(c) This line item includes in 2019 the favorable impact of top-up pension plan amendments following the application of the Pacte law in France.

The table below shows the aggregate obligation as of December 31 for each period presented for individuals who hold or have held executive positions within Sanofi during that period.

(€ million)	2021	2020 [(a)]	2019 [(a)]
Aggregate top-up pension obligation in favor of certain corporate officers and of Executive Committee members	28	32	48
Aggregate termination benefits and lump-sum retirement benefits in favor of key management personnel	7	5	4

(a) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (see Note A.2.1.).

D.34. Disclosures about major customers and credit risk

Credit risk is the risk that customers (wholesalers, distributors, pharmacies, hospitals, clinics or government agencies) may fail to pay their debts; for Sanofi, that risk is mainly concentrated on amounts receivable from wholesalers in the United States. Sanofi manages credit risk by vetting customers in order to set credit limits and risk levels, and asking for guarantees or insurance where necessary; performing controls; and monitoring qualitative and quantitative indicators of accounts receivable balances, such as the period of credit taken and overdue payments.

Sales generated by Sanofi with its biggest customers, in particular certain wholesalers in the United States, represented 23% of net sales in 2021. The three largest customers respectively accounted for approximately 10%, 7% and 6% of Sanofi's net sales in 2021 (10%, 6% and 5% in 2020; 8%, 5% and 3% in 2019).

D.35. Segment information

As indicated in Note B.26., Sanofi has three operating segments: Pharmaceuticals, Vaccines, and Consumer Healthcare.

The Pharmaceuticals segment comprises, for all geographical territories, the commercial operations of the following global franchises: Specialty Care (Dupixent®, Neurology & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders) and General Medicines (Diabetes, Cardiovascular, and Established Prescription Products), together with research, development and production activities dedicated to the Pharmaceuticals segment. This segment also includes associates whose activities are related to pharmaceuticals. Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.2.). Consequently, the Pharmaceuticals segment no longer includes Sanofi’s equity-accounted share of Regeneron’s profits for all the periods presented in that note.

The Vaccines segment comprises, for all geographical territories, the commercial operations of Sanofi Pasteur, together with research, development and production activities dedicated to vaccines.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for Sanofi’s Consumer Healthcare products, together with research, development and production activities dedicated to those products.

Inter-segment transactions are not material.

The costs of global support functions (External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.) are managed centrally at group-wide level. The costs of those functions are presented within the “Other” category. That category also includes other reconciling items such as retained commitments in respect of divested activities.

Following the Capital Markets Day held in February 2021, Sanofi changed the presentation of net sales within the General Medicines franchises and the Consumer Healthcare segment, and also reallocated certain expenses. In particular, IT costs relating to Sanofi's new digital organization – previously allocated to the Pharmaceuticals, Vaccines, and Consumer Healthcare segments – are now included within the “Other” segment. The 2020 segmental results presented below have been amended for comparative purposes in order to reflect those adjustments. Due to a lack of available data and the excessive complexity of the adjustments that would be required (especially to Sanofi's reporting tools), costs for 2019 have not been amended to reflect the changes arising from this new organization.

In accordance with IAS 8, Sanofi has treated the first-time application of the IFRIC agenda decisions on (i) the calculation of provisions for pensions and other post-employment benefits under IAS 19 and (ii) accounting for costs of configuring or customising a supplier’s application software in a Software as a Service (SaaS) arrangement as retrospective changes in accounting policy. The impacts of those IFRIC agenda decisions are presented in Note A.2.1.

D.35.1. Segment results

D.35.1.1. Analysis of net sales

The table below sets forth Sanofi's net sales for the years ended December 31, 2021, 2020 and 2019:

(€ million)		Europe	United States	Other countries	2021	Europe	United States	Other countries	2020	Europe	United States	Other countries	2019
Pharmaceuticals		**7,201**	**10,484**	**9,285**	**26,970**	**6,819**	**9,635**	**9,220**	**25,674**	**6,797**	**8,918**	**9,985**	**25,700**
General Medicines		**4,437**	**2,637**	**7,144**	**14,218**	**4,505**	**2,869**	**7,346**	**14,720**	**4,809**	**3,386**	**8,342**	**16,537**
of which	Lantus®	474	861	1,159	2,494	537	929	1,195	2,661	599	1,149	1,264	3,012
	Toujeo®	394	259	316	969	374	267	292	933	343	289	251	883
	Praluent®	161	5	52	218	119	106	34	259	112	112	34	258
	Multaq®	22	292	15	329	24	274	14	312	41	295	11	347
	Lovenox®	703	29	754	1,486	656	30	665	1,351	730	33	596	1,359
	Plavix® [(a)]	115	9	805	929	126	10	777	913	141	—	1,192	1,333
	Generics[(a)]	7	117	575	699	10	161	637	808	9	152	740	901
	Industrial sales	723	41	44	808	658	67	88	813	599	56	103	758
Specialty Care		**2,764**	**7,847**	**2,141**	**12,752**	**2,314**	**6,766**	**1,874**	**10,954**	**1,988**	**5,532**	**1,643**	**9,163**
of which	Aubagio®	512	1,312	131	1,955	473	1,448	124	2,045	414	1,351	114	1,879
	Cerezyme®	244	173	266	683	249	177	264	690	259	184	265	708
	Myozyme®/ Lumizyme®	410	373	220	1,003	389	359	200	948	388	331	199	918
	Fabrazyme®	223	395	226	844	200	406	211	817	185	410	218	813
	Eloctate®	—	429	134	563	—	445	193	638	—	517	167	684
	Jevtana®	112	253	90	455	187	246	103	536	170	212	102	484
	Dupixent®	649	3,971	629	5,249	386	2,808	340	3,534	204	1,669	201	2,074
Vaccines		**1,225**	**2,762**	**2,336**	**6,323**	**973**	**2,759**	**2,241**	**5,973**	**851**	**2,733**	**2,147**	**5,731**
of which	Polio/Pertussis/ Hib Vaccines	306	470	1,383	2,159	331	412	1,363	2,106	315	380	1,251	1,946
	Influenza Vaccines	729	1,366	533	2,628	441	1,575	456	2,472	230	1,289	372	1,891
Consumer Healthcare[(b)]		**1,333**	**1,139**	**1,996**	**4,468**	**1,359**	**1,071**	**1,964**	**4,394**	**1,434**	**1,105**	**2,156**	**4,695**
of which	Allergy	49	371	192	612	51	361	205	617	53	323	231	607
	Pain Care	515	196	382	1,093	481	181	389	1,051	482	185	427	1,094
	Digestive Wellness	389	124	618	1,131	371	85	532	988	377	150	577	1,104
Total net sales		**9,759**	**14,385**	**13,617**	**37,761**	**9,151**	**13,465**	**13,425**	**36,041**	**9,082**	**12,756**	**14,288**	**36,126**

(a) Following the Capital Markets Day held in February 2021, Sanofi has altered the presentation of sales within the General Medicines franchises and the Consumer Healthcare segment. A separate line has been introduced for "Industrial sales", which essentially comprises sales of active ingredients and semi-finished products to third parties. Previously, such sales were presented within the Diabetes and Cardiovascular & Established Prescription Products franchises on the line for the relevant product (such as Plavix®), and on the "Generics" line.

(b) For the Consumer Healthcare GBU, Sanofi has adopted a more granular presentation by introducing new sub-categories that reflect consumer trends and the strengths and opportunities of the portfolio.

D.35.1.2. Business operating income

Sanofi reports segment results on the basis of "Business operating income". This indicator is used internally by Sanofi's chief operating decision maker to measure the performance of each operating segment and to allocate resources.

Following the Capital Markets Day held in February 2021, Sanofi reallocated certain expenses. In particular, IT costs relating to Sanofi's new digital organization – previously allocated to the Pharmaceuticals, Vaccines, and Consumer Healthcare segments – are now included within the "Other" segment. The 2020 segmental results presented below have been amended for comparative purposes in order to reflect those adjustments. Due to a lack of available data and the excessive complexity of the adjustments that would be required (especially to Sanofi's reporting tools), costs for 2019 have not been amended to reflect the changes arising from this new organization.

"Business operating income" is derived from ***Operating income***, adjusted as follows:

- the amounts reported in the line items ***Restructuring costs and similar items***, ***Fair value remeasurement of contingent consideration*** relating to business combinations or divestments and ***Other gains and losses, and litigation*** are eliminated;
- amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature) are eliminated;
- the share of profits/losses from investments accounted for using the equity method is added (for 2020, excludes Regeneron up to and including May 29, 2020; see Note D.2.);
- net income attributable to non-controlling interests is deducted;

- other acquisition-related effects (primarily the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments accounted for using the equity method) are eliminated;
- restructuring costs relating to investments accounted for using the equity method are eliminated; and
- in 2020, the gain on the divestment of Regeneron shares on May 29, 2020 is eliminated (this elimination does not include the gain on the remeasurement of the 400,000 retained shares at market value as of that date).

The table below sets forth Sanofi's segment results for the years ended December 31, 2021, December 31, 2020 and December 31, 2019:

	2021				
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Other [a]	Total Sanofi
Net sales	**26,970**	**6,323**	**4,468**	**—**	**37,761**
Other revenues	264	1,095	55	—	1,414
Cost of sales	(6,965)	(3,430)	(1,606)	(250)	(12,251)
Research and development expenses	(4,330)	(712)	(153)	(497)	(5,692)
Selling and general expenses	(5,326)	(805)	(1,388)	(2,036)	(9,555)
Other operating income and expenses	(1,172)	128	111	(13)	(946)
Share of profit/(loss) from investments accounted for using the equity method	17	11	11	—	39
Net income attributable to non-controlling interests	(49)	(1)	(5)	(1)	(56)
Business operating income	**9,409**	**2,609**	**1,493**	**(2,797)**	**10,714**

(a) This caption reconciles segment financial information to total consolidated financial information.

	2020[a][b]				
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Other [c]	Total Sanofi
Net sales	**25,674**	**5,973**	**4,394**	**—**	**36,041**
Other revenues	128	1,141	59	—	1,328
Cost of sales	(6,982)	(3,312)	(1,528)	(284)	(12,106)
Research and development expenses	(4,171)	(682)	(153)	(524)	(5,530)
Selling and general expenses	(4,927)	(789)	(1,419)	(2,256)	(9,391)
Other operating income and expenses	(487)	3	53	(130)	(561)
Share of profit/(loss) from investments accounted for using the equity method	5	2	9	—	16
Net income attributable to non-controlling interests	(33)	—	(5)	—	(38)
Business operating income	**9,207**	**2,336**	**1,410**	**(3,194)**	**9,759**

(a) 2020 figures have been adjusted to take account of the reallocation of certain expenses (in particular IT costs related to Sanofi's new digital organization) from the Pharmaceuticals, Vaccines and Consumer Healthcare operating segments to the "Other" segment.
(b) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (see Note A.2.1.).
(c) This caption reconciles segment financial information to total consolidated financial information.

	2019[a]				
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Other [b]	Total Sanofi
Net sales	**25,700**	**5,731**	**4,695**	**—**	**36,126**
Other revenues	173	1,275	57	—	1,505
Cost of sales	(6,751)	(3,373)	(1,599)	(253)	(11,976)
Research and development expenses	(4,851)	(639)	(149)	(381)	(6,020)
Selling and general expenses	(5,443)	(823)	(1,529)	(2,089)	(9,884)
Other operating income and expenses	(630)	(4)	193	17	(424)
Share of profit/(loss) from investments accounted for using the equity method	5	9	(5)	—	9
Net income attributable to non-controlling interests	(29)	—	(6)	—	(35)
Business operating income	**8,174**	**2,176**	**1,657**	**(2,706)**	**9,301**

(a) Includes the impact of the April 2021 IFRIC agenda decision on the allocation of benefits to service periods (see Note A.2.1.).
(b) This caption reconciles segment financial information to total consolidated financial information.

The table below, presented in compliance with IFRS 8, shows a reconciliation between aggregated "Business operating income" for the segments and ***Income before tax and investments accounted for using the equity method:***

(€ million)	2021	2020 [f]	2019 [f]
Business operating income	**10,714**	**9,759**	**9,301**
Share of profit/(loss) from investments accounted for using the equity method[a]	(39)	(16)	(9)
Net income attributable to non-controlling interests[b]	56	38	35
Amortization and impairment of intangible assets	(1,772)	(2,011)	(5,750)
Fair value remeasurement of contingent consideration	(4)	124	238
Expenses arising from the impact of acquisitions on inventories[c]	(4)	(53)	(3)
Restructuring costs and similar items	(820)	(1,089)	(1,088)
Other expenses related to business combinations	—	—	—
Other gains and losses, and litigation[d]	(5)	136	327
Gain on divestment of Regeneron shares on May 29, 2020[e]	—	7,225	—
Operating income	**8,126**	**14,113**	**3,051**
Financial expenses	(368)	(388)	(440)
Financial income	40	53	141
Income before tax and investments accounted for using the equity method	**7,798**	**13,778**	**2,752**

(a) Excludes restructuring costs relating to investments accounted for using the equity method and expenses arising from the impact of acquisitions on investments accounted for using the equity method. For 2019 and the first two quarters of 2020, this line has been restated to exclude any effect of equity method accounting for the investment in Regeneron following the divestment of Sanofi's entire equity interest (with the exception of the 400,000 shares retained by Sanofi) on May 29, 2020.

(b) Excludes (i) restructuring costs and (ii) other adjustments attributable to non-controlling interests.

(c) This line records the impact of the workdown of acquired inventories remeasured at fair value at the acquisition date.

(d) For 2020, this line mainly comprises the gain on the sale of operations related to the Seprafilm® activity to Baxter. For 2019, this line comprises a net gain, mainly arising from a settlement of litigation.

(e) This line includes the gain on the sale of (i) 13 million shares of Regeneron common stock in the registered public offering and (ii) the 9.8 million shares repurchased by Regeneron, but does not include the gain arising from the remeasurement of the 400,000 retained shares at market value as of May 29, 2020.

(f) Includes the impacts of the IFRIC final agenda decisions of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement and of April 2021 on the attribution of benefits to periods of service, as described in Note A.2.1.

D.35.2. Other segment information

The tables below show the split by operating segment of (i) the carrying amount of investments accounted for using the equity method, (ii) acquisitions of property, plant and equipment, and (iii) acquisitions of intangible assets.

The principal investments accounted for using the equity method in the Pharmaceuticals segment are entities majority owned by MSP Vaccine Company, and Infraserv GmbH & Co. Höchst KG.

Acquisitions of intangible assets and property, plant and equipment correspond to acquisitions paid for during the period.

	2021			
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Total
Investments accounted for using the equity method	165	85	—	250
Acquisitions of property, plant and equipment	1,024	382	73	1,479
Acquisitions of other intangible assets	450	108	6	564

	2020			
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Total
Investments accounted for using the equity method	154	47	—	201
Acquisitions of property, plant and equipment	755	404	95	1,254
Acquisitions of other intangible assets[a]	501	322	6	829

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.)

	2019			
(€ million)	Pharmaceuticals	Vaccines	Consumer Healthcare	Total
Investments accounted for using the equity method	205	40	4	249
Acquisitions of property, plant and equipment	773	462	88	1,323
Acquisitions of other intangible assets[(a)]	292	121	51	464

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.)

D.35.3. Information by geographical region

The geographical information on net sales provided below is based on the geographical location of the customer. In accordance with IFRS 8, the non-current assets reported below exclude right-of-use assets relating to leases as determined under IFRS 16, investments accounted for using the equity method, other non-current assets, non-current income tax assets, and deferred tax assets.

	2021					
(€ million)	Total	Europe	of which France	North America	of which United States	Other countries
Net sales	**37,761**	**9,759**	**2,256**	**15,075**	**14,385**	**12,927**
• property, plant and equipment owned	10,028	5,959	3,253	2,998	2,234	1,071
• goodwill	48,056	—	—	—	—	—
▪ other intangible assets	21,407	7,059	—	13,187	—	1,161

	2020					
(€ million)	Total	Europe	of which France	North America	of which United States	Other countries
Net sales	**36,041**	**9,151**	**2,223**	**14,060**	**13,465**	**12,830**
• property, plant and equipment owned	9,365	5,895	3,189	2,542	1,899	928
• goodwill	44,364	—	—	—	—	—
• other intangible assets[(a)]	18,341	6,208	—	10,665	—	1,468

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.).

	2019					
(€ million)	Total	Europe	of which France	North America	of which United States	Other countries
Net sales	**36,126**	**9,082**	**2,261**	**13,370**	**12,756**	**13,674**
• property, plant and equipment owned	9,717	5,827	3,141	2,862	2,264	1,028
• goodwill	44,519	—	—	—	—	—
• other intangible assets[(a)]	16,509	6,890	—	7,813	—	1,806

(a) Includes the impact of the IFRIC agenda decision of March 2021 on the costs of configuring or customising application software used in a Software as a Service (SaaS) arrangement (see Note A.2.1.)

As stated in Note D.5., goodwill is not allocated by geographical region.

E/ Principal accountants' fees and services

PricewaterhouseCoopers Audit and Ernst & Young et Autres served as independent auditors of Sanofi for the year ended December 31, 2021 and for all other reporting periods presented. The table below shows fees charged by those firms and member firms of their networks to Sanofi and consolidated subsidiaries in the years ended December 31, 2021 and 2020.

	Ernst & Young				PricewaterhouseCoopers			
	2021		2020		2021		2020	
(€ million)	Amount	%	Amount	%	Amount	%	Amount	%
Audit: Statutory audit of separate and consolidated financial statements[(a)]	13.9	82%	13.9	82%	13.8	97%	15.1	98%
Services other than statutory audit[(b)]	3.0	18%	3.1	18%	0.4	3%	0.3	2%
Audit-related services[(c)]	2.8		2.5		0.4		0.2	
Tax	0.0		—		0.0		—	
Other	0.2		0.6		—		0.1	
Total	**16.9**	**100%**	**17.0**	**100%**	**14.2**	**100 %**	**15.4**	**100%**

(a) Includes services provided by the independent auditors of the parent company and French subsidiaries: Ernst & Young €7.2 million in 2021, €7.4 million in 2020; PricewaterhouseCoopers €7.7 million in 2021, €8.2 million in 2020.

(b) Services other than statutory audit provided by Ernst & Young et Autres during 2021 comprised:

- work on share capital transactions and securities issues submitted to the Annual General Meeting (in extraordinary business) for approval;

- additional procedures to enable reports previously signed by the firm to be incorporated by reference;

- agreed-upon and audit procedures in connection with a proposed divestment; and

- issuance of the Independent third party's report on the consolidated statement of extra-financial performance.

Services other than statutory audit provided by PricewaterhouseCoopers Audit during 2021 comprised:

- work on share capital transactions and securities issues submitted to the Annual General Meeting (in extraordinary business) for approval;

- additional procedures to enable reports previously signed by the firm to be incorporated by reference;

- contractual audits, assurance engagements, agreed-upon procedures and technical consultancy.

(c) Includes services provided by the independent auditors of the parent company and French subsidiaries: Ernst & Young: €2.7 million in 2021, €2.4 million in 2020; PricewaterhouseCoopers €0.3 million in 2021, €0.2 million in 2020.

Audit Committee pre-approval and procedures

The Audit Committee of Sanofi has adopted a policy and established certain procedures for the approval of audit services and for the pre-approval of other services to be provided by the independent auditors. In 2021, the Audit Committee established a limit for permitted audit-related and other services (i.e. services other than statutory audit) that can be provided by the independent auditors, and the related fees.

F/ List of principal companies included in the scope of consolidation during 2021

F.1. Principal fully consolidated companies

The table below shows the principal subsidiaries and their country of incorporation:

Europe		Financial interest (%) as of December 31, 2021
Hoechst GmbH	Germany	100.0
Sanofi-Aventis Deutschland GmbH	Germany	100.0
A. Nattermann & Cie. GmbH	Germany	100.0
EUROAPI Germany	Germany	100.0
Sanofi-Aventis GmbH	Austria	100.0
Sanofi Belgium	Belgium	100.0
Ablynx N.V.	Belgium	100.0
Genzyme Flanders BVBA	Belgium	100.0
Sanofi A/S	Denmark	100.0
Sanofi-Aventis S.A.	Spain	100.0
Sanofi Oy	Finland	100.0
Sanofi	France	100.0
Sanofi-Aventis France	France	100.0
Sanofi Winthrop Industrie	France	100.0
Sanofi-Aventis Recherche & Développement	France	100.0
Sanofi-Aventis Groupe	France	100.0
Sanofi Chimie	France	100.0
Francopia	France	100.0
Sanofi-Aventis Participations	France	100.0
Genzyme Polyclonals SAS	France	100.0
Sanofi Pasteur	France	100.0
Aventis Pharma S.A.	France	100.0
Sanofi Biotechnology	France	100.0
Sanofi Mature IP	France	100.0
Sanofi Pasteur NVL	France	100.0
Sanofi Vaccine Technologies	France	100.0
Sanofi Pasteur Europe	France	100.0
SECIPE SAS	France	100.0
Sanofi Pasteur Merieux S.A.S.	France	100.0
Sanofi 2015 D SAS	France	100.0
Opella Healthcare International SAS	France	100.0
Opella Healthcare France SAS	France	100.0
EUROAPI	France	100.0
EUROAPI France	France	100.0
Sanofi-Aventis A.E.B.E.	Greece	100.0
Sanofi-Aventis Private Co, Ltd	Hungary	99.6
Chinoin Private Co. Ltd	Hungary	99.6
EUROAPI Hungary Kft.	Hungary	100.0
Opella Healthcare Hungary K.F.T	Hungary	100.0
Carraig Insurance DAC	Ireland	100.0
Sanofi-Aventis Ireland Ltd	Ireland	100.0
Genzyme Ireland Limited	Ireland	100.0
Sanofi Finance Ireland limited	Ireland	100.0
Sanofi-aventis Holdings (Ireland) Ltd	Ireland	100.0
Sanofi S.R.L.	Italy	100.0
EUROAPI Italy SRL	Italy	100.0
Genzyme Global Sarl	Luxembourg	100.0
Genzyme Luxembourg Sarl	Luxembourg	100.0
Genzyme Europe B.V.	Netherlands	100.0
Sanofi Foreign Participations B.V.	Netherlands	100.0
Kiadis Pharma N.V.	Netherlands	97.4

Europe		Financial interest (%) as of December 31, 2021
Kiadis Pharma Holding B.V.	Netherlands	97.4
Sanofi-Aventis Sp. z.o.o.	Poland	100.0
Sanofi Produtos Farmaceuticos Lda	Portugal	100.0
Sanofi-Aventis, s.r.o.	Czech Republic	100.0
Sanofi Romania SRL	Romania	100.0
Sanofi-Aventis UK Holdings Limited	United Kingdom	100.0
Euroapi UK Ltd.	United Kingdom	100.0
Aventis Pharma Limited	United Kingdom	100.0
Sanofi-Synthelabo UK Ltd	United Kingdom	100.0
Hoechst Marion Roussel Ltd	United Kingdom	100.0
Aventis Pharma Holdings Ltd	United Kingdom	100.0
AO Sanofi Russia	Russia	100.0
CJSC Sanofi-Aventis Vostok	Russia	100.0
sanofi-aventis Slovakia s.r.o.	Slovakia	100.0
Sanofi AB	Sweden	100.0
Sanofi-Aventis (Suisse) SA	Switzerland	100.0
Genzyme Global Sarl Baar Intellectual Property Branch	Switzerland	100.0
Sanofi Ilac Sanayi ve Ticaret A.S.	Turkey	100.0
Sanofi Pasteur Asi Ticaret A.S.	Turkey	100.0
Sanofi Saglik Urunleri Limited Sirketi	Turkey	100.0
Limited Liability Company Sanofi-Aventis Ukraine	Ukraine	100.0

United States		Financial interest (%) as of December 31, 2021
Genzyme Therapeutic Products Limited Partnership	United States	100.0
Aventis Inc.	United States	100.0
Sanofi US Services Inc.	United States	100.0
Sanofi-Aventis U.S. LLC	United States	100.0
Chattem, Inc.	United States	100.0
Aventisub LLC	United States	100.0
Genzyme Corporation	United States	100.0
Sanofi Pasteur Inc.	United States	100.0
VaxServe, Inc.	United States	100.0
Bioverativ Inc.	United States	100.0
Bioverativ U.S. LLC	United States	100.0
Bioverativ Therapeutics Inc.	United States	100.0
Principia Biopharma Inc.	United States	100.0
Sanofi Research Invest LLC	United States	100.0
Translate Bio MA, Inc.	United States	100.0
Translate Bio Securities Corpo	United States	100.0
Sanofi Bioverativ Holdings LLC	United States	100.0
RPR US Ltd.	United States	100.0
Kadmon Holdings, Inc.	United States	100.0
Kadmon Corporation, LLC	United States	100.0

Other Countries		Financial interest (%) as of December 31, 2021
Sanofi-Aventis South Africa (Pty) Ltd	South Africa	100.0
Sanofi-Aventis Algérie	Algeria	100.0
Sanofi Arabia Trading Company Limited	Saudi Arabia	75.0
Sanofi-Aventis Argentina S.A.	Argentina	100.0
Genzyme de Argentina S.A.	Argentina	100.0
Sanofi-Aventis Healthcare Pty Ltd	Australia	100.0
Sanofi-Aventis Australia Pty Ltd	Australia	100.0
Sanofi Medley Farmaceutica Ltda	Brazil	100.0
Sanofi-Aventis Canada Inc.	Canada	100.0
Sanofi Pasteur Limited	Canada	100.0
Sanofi-Aventis de Chile S.A.	Chile	100.0
Sanofi (Hangzhou) Pharmaceuticals Co., Ltd	China	100.0
Sanofi (China) Investment Co., Ltd	China	100.0
Sanofi (Beijing) Pharmaceuticals Co.Ltd	China	100.0
Sanofi Pasteur Biologies Co., Ltd	China	100.0
Shenzhen Sanofi pasteur Biological Products Co, Ltd	China	100.0
Shanghai Rongheng Pharmaceutical Co, Ltd	China	100.0
Genfar S.A.	Colombia	100.0
Sanofi-Aventis de Colombia S.A.	Colombia	100.0
Sanofi-Aventis Korea Co. Ltd	South Korea	100.0
Sanofi Pasteur Ltd	South Korea	100.0
Sanofi-Aventis Gulf FZE	United Arab Emirates	100.0
Sanofi Egypt	Egypt	99.8
Sanofi Hong-Kong Limited	Hong Kong	100.0
Sanofi India Limited	India	60.4
Sanofi Healthcare India Private Limited	India	99.9
PT Aventis Pharma	Indonesia	80.0
Sanofi-Aventis Israël Ltd	Israel	100.0
Sanofi K.K.	Japan	100.0
SSP Co.,Ltd	Japan	100.0
Sanofi Nichi-Iko K.K.	Japan	51.0
Sanofi-Aventis (Malaysia) SDN. BHD.	Malaysia	100.0
Sanofi-Aventis Maroc	Morocco	100.0
Sanofi-Aventis de Mexico S.A. de C.V.	Mexico	100.0
Sanofi-Aventis Winthrop S.A. de C.V.	Mexico	100.0
Sanofi Pasteur S.A. de C.V.	Mexico	100.0
Azteca Vacunas, S.A. de C.V.	Mexico	100.0
Sanofi-Aventis Pakistan Limited	Pakistan	52.9
Sanofi-Aventis de Panama S.A.	Panama	100.0
sanofi-aventis Puerto Rico Inc	Puerto Rico	100.0
Sanofi-Aventis Philippines Inc.	Philippines	100.0
Sanofi Pasteur Inc (Philippines)	Philippines	100.0
Sanofi-Aventis Singapore Pte. Ltd	Singapore	100.0
Aventis Pharma (Manufacturing) Pte. Ltd	Singapore	100.0
Sanofi Taiwan Co., Ltd	Taiwan	100.0
Sanofi-Aventis (Thailand) Ltd	Thailand	100.0
Sanofi-Aventis de Venezuela S.A.	Venezuela	100.0
Sanofi-aventis Vietnam Company Limited	Vietnam	100.0
Sanofi Vietnam Shareholding Company Limited	Vietnam	85.0

F.2. Principal investments accounted for using the equity method

		Financial interest (%) as of December 31, 2021
GlaxoSmithKline Consumer Healthcare, L.P.	United States	11.7
Infraserv GmbH & Co. Höchst KG	Germany	31.2
Maphar	Morocco	48.3
MCM Vaccine B.V.	Netherlands	50.0
MSP Vaccine Company (formerly MCM company)	United States	50.0

G/ Events subsequent to December 31, 2021

On January 7, 2022, Sanofi announced an innovative research collaboration and license agreement with Exscientia to develop up to 15 novel small molecule candidates across oncology and immunology, leveraging Exscientia's end-to-end AI-driven platform utilizing actual patient samples. Under the terms of the agreement, Exscientia will receive an upfront cash payment of $100 million from Sanofi, with the potential for up to $5.2 billion in total milestones plus tiered royalties.

On January 11, 2022, Sanofi entered into a licensing agreement with ABL Bio for the development of ABL301, a potential first-in-class bispecific antibody targeting alpha-synuclein and containing a proprietary brain shuttle, for alpha-synucleinopathies, including Parkinson's disease. ABL Bio will receive $75 million upfront and up to $985 million in potential milestone payments for an exclusive global license to ABL301.

Apart from these events, no other significant events occurred between the end of the reporting period and the date on which the consolidated financial statements were signed off by the Board of Directors.

Notes

Notes

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